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Proceedings of the 1982 Meetings of the Chairpersons of NIH Scientific Review Groups

Prepared by:
Division of Research Grants

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service National Institutes of Health

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I

PREFACE

In order to continue the highly successful 1981 meetings with the Chairpersons of the NIH scientific review groups, the NIH held two such gatherings in February 1982. Those review groups that were not represented during the 1981 meetings were invited to send their chairpersons to participate in the 1982 discussions about the peer review system. From the viewpoint of the NIH, the meetings were extremely worthwhile, and we plan to hold such forums in the future. We hope that these Proceedings, which record in some detail the topics discussed, will prove useful to everyone interested in the peer review system used at the NIH.

Carl D. Douglass, Ph.D.
Director, Division of Research Grants

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I. INTRODUCTION

The February 1 and 8, 1982 Chairpersons Meetings were the most recent in a series of informal discussions between representatives of the NIH administration and the chairpersons of the NIH scientific review groups. Sponsored by the Associate Director for Extramural Research and Training, NIH, these meetings provided a forum for the chairpersons to voice their concerns about, and suggest refinements of, the peer review system.

Besides the chairpersons, the following NIH representatives attended the meetings: Dr. Thomas E. Malone, Acting Director; Dr. William F. Raub, Associate Director for Extramural Research and Training; Dr. Carl D. Douglass, Director, Division of Research Grants; Dr. S. Stephen Schiaffino, Deputy Director, Division of Research Grants; Dr. Samuel M. Schwartz, Associate Director for Scientific Review, Division of Research Grants; Dr. Charles R. McCarthy, Director, Office for Protection from Research Risks; Dr. John Petricciani, Assistant Director for Medical Affairs, Office for Protection from Research Risks; executive secretaries of the scientific review groups; and administrators from the Bureaus, Institutes, and Divisions. A complete list of the participants is included in Appendix A.

The agenda for the meetings was as follows:

- 10:00 a.m.: Welcome and Introduction
  Drs. Raub and Douglass
- 10:15 a.m.: Impact of Recent Events on the NIH
  Dr. Malone
- 11:00 a.m.: Panel Discussion
  Drs. Raub, Douglass, Schiaffino, Schwartz, and Chairpersons
- 12:00 noon: Regulations Regarding Human and Animal Subjects Involved in Research
  Drs. McCarthy and Petricciani
- 12:30 p.m.: Lunch
- 1:30 p.m.: Panel Discussion
  Drs. Raub, Douglass, Schiaffino, Schwartz, and Chairpersons
- 3:30 p.m.: Adjournment

Discussion topics were chosen from a list of items solicited from the chairpersons and other scientific review group members.

To avoid repetition and to clarify the comments, we have merged the proceedings from the two meetings into one volume. For the same reasons, we have organized the unstructured panel discussions into subject areas. Because it was impossible to identify most of the speakers, we have divided the panel discussions into anonymous comments or questions from chairpersons and responses from NIH staff.

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II. IMPACT OF RECENT EVENTS ON THE NIH
Dr. Thomas E. Malone, Acting Director, NIH

Let me say at the outset that the NIH is an extremely healthy place. Even though we do not have a permanent director, have a number of key vacancies in many of the Institutes, and have an Acting Deputy Director for Science, the business of the NIH goes on smoothly. We have seen no deceleration of pace during the last six months since I have been the Acting Director, thanks to a remarkable collusion of effort by NIH staff and by all in the external community. The new NIH Director will find things in fairly good circumstances.

We have also had extraordinarily good support from and cooperation with the Public Health Service, the Assistant Secretary for Health, the Secretary, and other people new in this Administration. This support has come directly from Ed Brandt (Assistant Secretary for Health), who interacts with us on a daily basis and understands the NIH; from his staff; and from the Secretary, who has carried the fight for the NIH budget directly to the Office of Management and Budget, where he has been extremely successful. While we have not gotten monies at this point to keep up with inflation, which obviously has great impact on the work that you do, it could have been, I assure you, a great deal worse.

Throughout our discussions with the Departmental staff, the budget task force, and the Secretary, we have steadfastly maintained that the purpose of the NIH, of biomedical research, is of equal if not greater importance than the defense effort and one in which this country cannot afford to lose its leadership.

We hope that, as in past years, the current budget presented by the President will be examined carefully by the Congress. Members of both Congressional appropriations committees may provide some incremental growth, understanding that we have not kept up with inflation, and that problems brought on by a period of austerity have to be dealt with. While we may get additional funds from Congress, we don't expect that any increase will be of the same magnitude as in prior years. The Congress must react within the realm of current economic constraints.

In reflecting on the budgetary cycle that we have just gone through, I would like to mention the NIH stabilization concept, that is NIH's commitment to underwrite a certain minimum number of new and competing research grants each year. This was an important innovation that we initiated during Dr. Donald Fredrickson's tenure here.

Some years ago when Mr. Joseph Califano was Secretary, many of you participated in a massive planning conference held at NIH. It was clear from that meeting and from discussions at that time that some principles had to be developed that would appeal to the Congress and the Administration, principles that would at a minimum preserve the level of biomedical research in this country.

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One of the principles that emerged was that we had to develop a model formulation for supporting a stable number of new and competing research grantees. The number 5,000 was chosen. This number was predicated on the fact that at any one time, the NIH has a portfolio of some 15,000 to 16,000 project grants. In duration these average about 3.1 years, which means that about one-third are new each year. So at a minimum we should be certain that this number is replaced.

Having gone through a series of budgetary meetings in the Public Health Service and in the Department for the 1983 budget, I can assure you that stabilization has been absolutely unquestioned by those who were the framers of the budget at all levels beyond NIH. We have also witnessed some relief in the stabilization of research manpower. While there may be some dickering about the envelope of institutional support, there is common agreement that we should support trainees somewhere at the level of 10,000 or 11,000 per year.

One offshoot of this initiative is that stabilization has differentially affected the rest of the NIH programs. The problem now is to maintain the protection that we have in the research grant and research manpower areas and to extend that protection to other elements of the NIH budget, such as contracts, clinical trials, centers, and intramural activities. Now this obviously is going to have to be done with some new imperatives, for as mentioned earlier, we are like everyone else caught up in the economic recovery program. I suspect we will have to make, in the next years ahead, decisions that we have never had to make before. The NIH will have to examine with its member Institutes the appropriate allocation of funds. We do not expect to see prospects for substantial growth over the next several years. As an example, we will probably not be able to conduct all the clinical trials that we should.

We are also under continuing pressure to translate and to transfer more of the results of research to the health care sector. We have a large base of research that relates to prevention, which is a strong initiative of Secretary Schweiker. While the Secretary is satisfied with our efforts so far, he is going to place increasing emphasis on an area which is a prime interest of his Administration. In line with this interest, we have appointed a Special Assistant in the Director's Office (Dr. John Seal) to deal with prevention activities. This individual is grappling with definitions and new coordinative efforts that he can bring about among the various Institutes. At the same time we will continue to capitalize on ongoing prevention activities, such as the Hypertension Program at the Heart Institute, the Nutrition Program, and the National Toxicology Program.

Another predominant interest of the Secretary is that of fiscal and scientific accountability. We are updating our policies and reviewing how to deal with those rare cases of scientific fraud and abuse. We have pointed out that if one looks at the thousands of projects supported by the NIH over the years and the extensive number of scientists participating in research, the cases of scientific fraud are miniscule. But all it takes is one case to bring down on us the wrath of the Congress, the Administration, and the General Accounting Office. We are now busy trying to determine how best we can deal with those who are found guilty of infractions while still preserving the scientific process.

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For the decade ahead, we have a whole host of problems. But we also have an unprecedented chance now to seize upon the results of the biomedical revolution, with the possibilities of recombinant DNA, with the great strides that have been made in immunology, with the potential for having by the year 2000 a bank of all of the human antibodies known through hybridoma techniques, and with elegant instrumentation such as the PETT scanner. Our challenge is to seize upon the unusual opportunities in biomedical research by getting as much as possible out of the budgetary structure, as much support as we can from the Congress, to see that during this period that we survive in as healthy a state as possible.

Thank you very much. Now I would be pleased to answer any questions.

A. DISCUSSION

Question: With respect to stability, rumors are that we are considerably below 5,000 grants at this point. It this true?

Dr. Malone: For 1982, we are at about 4,800. For 1983, although we are sworn to secrecy right now, the situation will be more stringent in terms of the Administration's budget. But, as in past years, we hope to have more favorable treatment by the Congress.

Question: I am pleased to hear that the perspective from Washington seems so positive. But certainly in my part of the country it is very hard to share that view. We are four months into the fiscal year, and I know of competing renewals and new applications that haven't received notice of grant awards yet, of projects that have lost personnel, of people who have decided not to follow biomedical research careers, and of medical centers that are changing their whole perspective on their ability to support research departments because of the administrative confusion that has occurred. I am not even talking about the funding level, but about the confusion since last October 1st. Will you address yourself to that issue?

Dr. Malone: These are not the best of times for anybody. But we have not done as badly as many of the other agencies in Government; in fact, we have seen some progression when there has been a retrenchment in other agencies. We are, in 1982, supporting somewhere on the order of 4,800 new research projects.

Of course, this has been a difficult budget year. We are under a continuing resolution, which is being changed constantly, and one doesn't know what is going to happen for the rest of the time. This is something that is entirely out of our control. But within the context of the economic recovery program of this Administration, we are not in the worst possible position, and I think that some of the problems you have mentioned go back many years.

And so I would prefer to be a bit more optimistic, realizing that what you have mentioned is fully understood by those of us who are here, that we make those points clear whenever we have an opportunity.

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Question: What do you think the prospects are for a real budget by March 31 rather than a continuing resolution?

Dr. Malone: I suspect that the continuing resolution will be continued for the rest of the year, but it is anybody's guess at this point. It is so late that I find it hard to believe that we will have a regular budget by March 31.

Question: Is there any reason for optimism because the President singled out NIH in the State of the Union Message?

Dr. Malone: Yes. He knows we exist. Recently we went to the White House to present some scientists who received awards, and the President went into some length in his speech about their accomplishments. I think that was a very positive statement, and it is the first time, to my knowledge, that we have been recognized this way in the State of the Union Message.

Question: In the past, the Executive Branch usually sent a budget to the Hill that was augmented by Congress. But this year, it looks as though the austerity of the entire country has led to support by Congress for reducing budgets. In my viewpoint, it will be more difficult to defend the NIH budget. Are there innovative ways in which the extramural community might assist in providing Congress with more information, ways that we could be of help to the NIH staff?

Dr. Malone: Presentations by scientific members to members of Congress are extremely important. We have not always been sensitive to this over the years, and such presentations in the past were often for "my particular research project," rather than for the whole scientific community.

We must point out the absolute necessity of this country maintaining leadership in world science, of biomedical research being as important as, if not more important than, defense. In fact, Secretary Schweiker has just sent a letter to every member on the Hill explaining the accomplishments of the NIH and the number of Nobel and other prize winners, and suggesting that we would be available to provide briefings to any staff member or Congressman about the NIH's accomplishments.

If it is done in the proper way, this education venture can be successful.

Question: The budgets for some Institutes have increased rather dramatically in recent years, while others have decreased substantially. The Institute to which an application is assigned can often determine whether that application will be funded. How are the budget figures arrived at, so that some Institutes have such a large decrease? This can have a dramatic effect on people who have, for example, competing renewals in that Institute.

Dr. Malone: When the budget for any given year is being developed, we get what is called our "mark" from the Department, which gets its "mark" from the Office of Management and Budget. Based upon past history, the NIH is given an overall budget with increments for each of the awarding Institutes. The NIH then sets the percentage of growth for the various Institutes.

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This year, for example, with some exceptions, increases average about 3 percent per Institute. In some instances you will see less than that. Thus the National Cancer Institute transferred the National Toxicology Program to the National Institute of Environmental Health Sciences, which means that Environmental Health Sciences will show an increase and Cancer a decrease. Also you will see a fairly large figure for the Fogarty International Center. But Fogarty has a budget of about $9,000,000, and an incremental increase of 10 percent isn't very much; we felt there were several areas that had leveled off or diminished and needed some growth. Sometimes there is a special mandate from the Congress that we have to pursue and which has to be accommodated. Nonetheless, what an Institute receives in any one year is based largely on the history of the prior years and its proportionate share of the incremental growth.

Question: You indicated there would be less activity in clinical trials in the future. Do you believe that some ongoing clinical trials will be discontinued in midstream? Also what is your best guess about continued funding for program projects and specialized centers?

Dr. Malone: With respect to your first question, we have now about 800 ongoing clinical trials, and I suspect that this level will be maintained. We simply cannot afford to stop a clinical trial in midstream unless, as in the case of the propranolol trial, it is discovered that the conclusions are prematurely evident.

With respect to the other support mechanisms that you mentioned, we will always have those activities as an extension of the basic research process. We need specialized centers to bring an interdisciplinary approach to activities once they have progressed beyond the point of information that is derived from basic research grants. The Institutes would have to decide with their Councils and advisory groups what balance they would like to have. But the Institute directors are terribly concerned and sensitive to this point and do not want the basic research structure to be advanced to the point of having a destructive impact on the other elements in the budget.

Question: A number of recent surveys indicate that about $865,000,000 from the private sector is now in biomedical research laboratories in universities and medical centers. A substantial amount of support is in basic research, in programs that deal with fundamental problems in cell and molecular biology and recombinant DNA.

This means that there is frequently dual funding in laboratories. Is the NIH generating some kind of general policy statement that could be issued to principal investigators and universities as to how they go about receiving both NIH and private sector funds without any possible conflicts of interest or other problems?

Dr. Malone: The support that you have mentioned is not widespread. At the moment, it involves only a few institutions such as Stanford, Massachusetts General, and Harvard.

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And certainly, support from industry cannot supplant what we are doing in the Federal Government. Ours is an open, free system of inquiry, while an industrial organization pours money into a university for its own purposes, perhaps thinking about the stockholders and profits.

Nonetheless, among the issues that the Director's Advisory Committee is looking at are the ethical and legal considerations facing the NIH and the university when there is a commingling of funds. We have brought together in the forum of the Director's Advisory Committee, members from industry and academic institutions to discuss a whole set of new problems that we have not had to face before. We don't have the answers yet, but we are aware of the problems, and we look to this group for some recommendations as to how to deal with them. You will find many of the issues outlined in the two volume report of the last Director's Advisory Committee meeting.

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III. REGULATIONS REGARDING HUMAN AND ANIMAL SUBJECTS INVOLVED IN RESEARCH

Dr. Charles R. McCarthy, Director
Office for Protection from Research Risks
Dr. John Petricciani, Assistant Director for Medical Affairs
Office for Protection from Research Risks

Dr. McCarthy: I would like to discuss briefly the issues of human subjects involved in research and animal welfare, and then ask Dr. Petricciani, who recently joined our staff, to add his comments. There is no way we can adequately treat all the issues in these areas, nor do I think it is essential that we do, as long as you know where to get information.

First, let me say a word about the concern we have for the care and use of vertebrate animals involved in the research that we review. While this has always been a major and deeply rooted concern of the NIH, during this past year, we have had additional attention focused on this area from several sources. One was the nationally publicized case involving the Institute for Behavioral Research here in Silver Spring, Maryland. An investigator was found guilty of six counts of cruelty to animals for negligence in maintaining his animal care facility. In the course of that investigation, we found it necessary to withdraw the animal assurance from that institution, and that incident has led the NIH to reexamine its policies concerning animal welfare.

In his presentation before Congress, Dr. Raub indicated that we would be looking into the matter of increased site visits to animal care facilities--perhaps on a randomized basis as well as for cause when complaints come to our attention.

Furthermore, we are reviewing, with the help of the Extramural Program Management Committee, the possibility of improved documentation on this issue. Although considerable attention is given to animal welfare concerns during the review of applications, some of this attention is not well documented. Therefore, it is often difficult for us to show to Congress and to animal welfare groups the extent of our concern. So, we will probably be making suggestions for improving the documentation of your animal welfare review in the near future.

We are also working with Division of Research Resources to publish a revised guide for the care and use of laboratory animals that will make even more explicit our policies. It is a little too early to predict exactly what the changes will be, but you will be notified about changes in this area when they occur.

In the area of human subjects, we published new regulations in the Federal Register of January 26, 1981. These became effective July 27, 1981.

The human subjects area has also been the center of increased public and Congressional attention. Additionally, we have had a number of hearings before the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. In fact, that Commission recently published its first Biennial Report in which it addresses the Department's system for protecting human subjects. Although the report

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is generally laudatory of our efforts, it contains nine recommendations for tightening that system and for expanding it into a cooperative venture with other Federal agencies. We are examining the report and dealing almost daily with staff of the Commission in trying to improve our oversight of protections for human subjects.

Congress has also taken a great interest in this topic. There have been hearings before Representatives Gore and Waxman and Senator Hawkins. We are constantly replying to Congressional inquiries, during some weeks replying to as many as 25 Congressional letters. This is evidence of high public interest in this subject.

Most recently, the General Accounting Office has begun to review the adequacy of our protections for human subjects. So, we find ourselves under the microscope not only from the President's Commission and the Congress, but also from the Government Accounting Office.

We ask the study sections to be particularly alert to both animal and human subjects issues as they arise, and to become familiar with the new regulations.

Part of the pressure on us has been not only to provide adequate protection for subjects who are at risk, but to reduce workloads for institutions where the subjects are found to be at little or no risk. Thus, the new regulations contain five broad exemptions from human subject review, mostly in the areas of the social and behavioral sciences, but with some overlap in the biomedical field. These exemptions are as follows:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests, (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(3) Research involving survey or interview procedures, except where all of the following conditions exist: (i) responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects; (ii) the subject's responses, if they became known outside the research, could reasonably place the subject at

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risk of criminal or civil liability or be damaging to the subject's financial standing or employability; and (iii) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. All research involving survey or interview procedures is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office.

(4) Research involving the observation (including observation by participants) of public behavior, except where all of the following conditions exist: (i) observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects; (ii) the observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability; and (iii) the research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.

(5) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

We have met with all of the Executive Secretaries of the NIH scientific review groups and explained in detail these regulations. The Executive Secretaries are asked to determine whether a claimed exemption is justified. If not, the Executive Secretary is instructed to get in touch with the investigator and the institution and to insist that the application be properly reviewed. If your Executive Secretary fails to meet this responsibility, we hope the Chairperson will raise the issue.

Those are some of the highlights of the regulations. I am going to ask Dr. Petricciani to talk about some of the other features associated with them.

Dr. Petricciani: I will just try to amplify several areas that Dr. McCarthy mentioned. First of all, the new regulations are congruent in virtually every respect with those of the FDA (Food and Drug Administration). However, the exemptions don't exist in the FDA regulations, because the FDA does not regulate behavioral or social science research; but the core elements of the regulations are virtually identical.

We are also in the process of revising the six points relating to human subjects that need to be addressed in every grant application involving human subjects. The revision will not be substantive; it will involve primarily clarifications. Those points will still need to be addressed in each application.

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One final area that I will discuss briefly is the risk-benefit analysis evaluation. As you all know, risk-benefit analyses are conducted at several different levels, starting with the principal investigator and moving through the institutional review board. But the scientific review group is also involved. The scientific review group's analysis of the risk-benefit ratio is of special importance for those institutions that do not have a general assurance with us, but we review all such comments on a case-by-case basis. We take those comments very seriously and will follow up on them.

In that regard, an important contribution in the evaluation of a proposal is any comment that the scientific review group may make regarding the qualifications of an investigator in a particular area of a proposal. The overall proposal may be quite acceptable, but there may be one or two subparts which, in the view of the group, are unlikely to be successful or pose risks. Integrating those comments into the overall benefit-risk assessment is of particular interest to us, especially in institutions that do not have a general assurance with us.

Comment: If the intent of the NIH is to try to remove some of the onerous burdens from the institutional review boards, one way to do this is to reduce some duplication of effort.

I think we would all agree that peer review should be the ultimate review of subject risk. These experts are well versed and interested in the particular area of research, and such a group is rarely, if ever, available in an institution. Certainly no institutional review board has expertise in all the research that is going on in that institution.

Yet at the present time, the institutional review board is given the responsibility of passing on subject risk on all peer-reviewed proposals. Furthermore, a proposal can't be funded until such a review has been carried out. This is obviously a duplication of effort and somewhat redundant. I would like to see some kind of a directive about administrative review of applications to be peer reviewed.

Dr. McCarthy: The National Commission, which met from roughly 1974 to 1978, reviewed the whole system and considered the kind of suggestions that you have made. One possibility was having an institutional review board look only at informed consent procedures and asking the peer review group to analyze risk-benefit ratios.

But the Commission recommended some redundancy in the review situation. Their feeling was that there are often local situations that the scientific review group cannot know about; while there is expertise in the scientific review group, which, as you pointed out, is seldom, if ever, found in the local boards. So, the two can reinforce each other. Each has a perspective that the other may lack.

In addition, the institutional review boards in most institutions review not only research that is to be funded by the NIH, but also other research carried out in the institution. Those applications that are not submitted for funding here would never receive peer review. So, somebody still would have to review them. Granted the review may not be at the same level of expertise as at the NIH, but it is a good deal better than no review at all.

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Those are some of the considerations that went into the recommendations of the Commission, recommendations which have also been endorsed by the reviewing committees in Congress.

Finally, since Nuremburg, there is a general tendency against placing any kind of central agency in a final decision-making position on the ethics of research. There is a strong inclination to disseminate this power, even though in some cases it may be less efficient.

Question: During project site visits, are the members of the team encouraged to inspect animal facilities and also get copies of the letters of assurance from the institutions?

NIH Response: At the moment, some of our site visits do not place a strong emphasis on the animal care as opposed to other aspects of the research; but in the future, I expect more emphasis will be given to this topic. We will be looking at whether site visitors can examine what the institution has pledged itself to in the assurance document and then evaluate whether the institution is living up to those commitments.

Comment: From the few site visits I participated in, I find that those letters reflect very well the situation and intent of the research project. I think it would be wise to have the assurance letter as part of the site visit package.

NIH Response: I believe that the Division of Research Resources, particularly with clinical research grants, routinely does that with their site visits. We plan to learn from the Division of Research Resources and possibly expand the technique.

NIH Response: In the Division of Research Grants, we are in the process of revising and strengthening the guidelines on the review of projects involving vertebrate animals, and these will be distributed to our review groups.

Question: Most applications contain a statement to the effect that NIH or some other society guidelines are being followed. With that general statement, how can the group fully handle animal welfare problems?

NIH Response: You can't come to grips with animal welfare problems in a total institutional setting when you are reviewing a project. You can, however, comment on what appears to be an excessive number of animals to be used in a project. Also, especially but not solely in the case of use of nonhuman primates, we ask you to discuss specifically whether this is an appropriate use of the animals, whether the procedures used are adequate, and whether any discomfort, pain or injury is minimized and is justifiable on the basis of the expected results.

In essence, you cannot get into the question of the institution's treatment of animals on a broad base. But you can address the question of the use of animals in a particular project. And that is where we ask you to be specific in your documentation.

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Dr. McCarthy: I will simply mention in connection with human subjects issues that we are trying to stress careful and sensitive review at every level. I think you are all aware of the kind of publicity that has recently occurred in the Washington Post, which I think cast a cloud over the adequacy of human subjects protections.* I think this is reflected in the hearings before the Congress, both with Representatives Gore and Waxman and also with Senator Hawkins. The entire scientific enterprise will be affected if we do a poor job in explaining to the Congress our concern for human subjects. So we are encouraging every level within the Department to be sensitive to these issues, and we are also launching a major educational program throughout the country to try to give additional sensitivity to institutional review boards, to research administrators, and to investigators.

*A reference to Dr. Kline at UCLA, who carried out human subjects research overseas without the required review by his institutional review board, to Dr. Straus of the New York Medical College, who also failed to obtain the approval of an institutional review board before conducting his research on human subjects, and to Phase I trials of anti-cancer drugs.

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IV. PANEL DISCUSSIONS

Dr. William F. Raub, Associate Director for Extramural Research and Training, NIH
Dr. Carl D. Douglass, Director, DRG
Dr. S. Stephen Schiaffino, Deputy Director, DRG
Dr. Samuel M. Schwartz, Associate Director for Scientific Review, DRG

A. INITIAL REVIEW PROCESS

1. Quality of Summary Statements

Comment: I have encountered a number of problems recently that relate to the fact that the summary statement often does not adequately reflect the discussion that went on during the review of the application. With the increasing number of good applications not being funded, applicants examine their summary statements to try to understand the reasons for the priority scores and are naturally disturbed if the summary statements contain contradictory or even inaccurate comments.

One explanation for this problem is that reviewers, in general, have the time during a meeting to correct only the grossest inaccuracies in written statements after the discussion of the application. Often nuances that are not properly reflective of all of the work are not deleted.

Although the Executive Secretary is supposed to handle this situation, it is difficult to incorporate notes that are taken during the discussion of an application into a statement which hangs together properly. What often happens is that the two assigned reviewers' written evaluations are spliced together in what seems to be an appropriate way. But when passages are taken out of context, the result may be apparently contradictory statements.

A possible resolution would be to give the primary reviewers an opportunity to review the draft of the summary statement before it is completed. The obvious disadvantage is the additional time needed to complete the summary statement. But I think that this is an important part of the review process, and if there could be time for a review of the summary statement before it is final, this would avert a number of current problems.

NIH Response: We are very much aware of and concerned about this situation. We ask our reviewers to incorporate any discussion changes in the written comments at the meeting; but, as you indicate, reviewers usually have limited time to do this.

In response to your suggestion, the Executive Secretaries are given 20 working days following the meeting to complete their summary statements. We follow this timetable closely because

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of the logistics of completing summary statements, sending them out to be printed, and then distributing them to the Institutes for the national advisory council or board meetings that take place two and a half months after the study section meetings. In reality, we need even more time to prepare summary statements.

While it would be nice to send drafts to members, logistically this is impossible. We just could not get them back in time to complete the process that has to take place in order for the national advisory council or board to consider them.

NIH Response: Executive Secretaries are writing about 21,000 summary statements a year now, and close attention to details is getting increasingly difficult. In my experience, the percentage of problems that we have in these summary statements is extremely small. I think that is not because the scientific community is averse to coming back at us, but because the overall quality of the summary statement is extremely good. I think the Executive Secretaries do a remarkable job of taking care of the very issues that you raise.

It is extremely difficult at meetings for Executive Secretaries to take adequate notes and for reviewers to check their comments completely. One device I have seen used is to have a third reviewer, who can balance the reviews of the two assigned reviewers or add a new point of view. Some Executive Secretaries have that particular reviewer write a critique, and send it in after the meeting to be incorporated into the summary statement.

Comment: To the extent that such critiques can be integrated into the summary statements, this will help the quality of summary statements. But I think one is still left with the fact that the final document is very carefully scrutinized by applicants, and unless it is reviewed at the NIH by someone who has an excellent understanding of the science, serious problems will continue to arise. While I agree this has not been a serious problem, I think its incidence is going to increase.

NIH Response: There are two types of problems: statements that because of language subtleties or lack of polish are misleading or antagonize the principal investigator; and statements that are sloppy or erroneous. Every Executive Secretary knows that all summary statements are not equally good. A handful will be mediocre at best. Often the problem comes when an Executive Secretary has material that seems unusable, either because it is badly written, folksy, contradictory, or just doesn't make sense. Then the summary statement may not reflect what happened at the meeting. It may contain partial information or be sloppy.

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Comment: I was trying to encompass several possible scenarios, but I did not mean to imply sloppy work. I think the Executive Secretary has an impossible task in trying to produce a statement that is a well-considered evaluation of the application and the discussion.

In its simplest form, the problem involves getting, very often, paragraphs from one review and intermingling them with another. And even though those individual reviews were self-consistent, when you combine the two, you come up with a paper that just doesn't strike the nail on the head anymore.

NIH Response: There is a way to do what you suggested. It won't help the individual, but it will help in the long haul. I request that after reviewers have read the summary statements from a previous meeting, they educate me and point out the things that I missed.

NIH Response: I would like to bring up a related issue that may help the situation. In some scientific review groups, members send in their reviews prior to the meeting. We have tended to discourage this practice after 1974 when the Privacy Act came into being. We felt that the danger of the raw reviews falling into the hands of the investigators was such that we didn't want them in our offices.

But I feel strongly that it is worth our getting the reviews in, even if this means having principal investigators request and see them. First of all, if any questions are brought up, the Executive Secretary can get the information before the meeting. Many hassles that occur at meetings can be avoided if the Executive Secretary has the information beforehand. Also, this ensures that the Executive Secretary has a copy of the member's review to read while the member is reading the review, and it is easier then for the Executive Secretary to incorporate any changes into the summary statement.

Now, of course, our responsibility is to send out the applications in sufficient time so that you can do this. Our practice was to get the applications to you 6 to 8 weeks prior to the meeting. We still try to accomplish this, but, as you all know, we are not succeeding as often as we would like. We have a manpower and logistic problem, but this is our responsibility. We must work to improve our mailings. But if you can get the reviews to us fairly early, I think the value to the Executive Secretary is immense.

Comment: If the Chairperson and the Executive Secretary are communicating well during the meeting, the Chairperson might alert the Executive Secretaries to potential problems.

Question: Would it be helpful in the partnership between the Executive Secretary and the Chairperson if, on a more routine

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basis, the review assignment decisions were shared prior to assigning an application? The question you raised is often caused by the variability of the opinions of the primary and secondary reviewers. Possibly the person who is in the field, the Chairperson, might be able to help with some of these potential mismatches. The Chairperson might suggest a third opinion.

NIH Response: That might help and, in fact, some Executive Secretaries already do that to some extent.

Comment: All of the actions we have discussed about what can be done through the review depend on the workload of the scientific review group and the Executive Secretary. My review group has an extremely heavy workload. I have had many complaints during the last meetings, and I am afraid we are going to lose people if things continue.

NIH Response: There is no easy solution for our workload. It is important to remember that the Executive Secretaries are professional staff, who, while they may not know in detail the whole of science, are generally able to understand the scientific areas covered by their study section. They use a variety of techniques, exercising that professional judgment through general knowledge and consulting with experts whenever necessary. With the kind of group we have, there are bound to be errors in the system, but generally it works amazingly well.

2. Priority Scores and Approval Rates

NIH Comment: We are concerned about the increasing approval rate and the way priority scores are being skewed to one end of the scale. About a third of the scores these days are in the 100 to 200 range, and approval rates are way up. For example, the current rate for applications coming in for competitive renewal is about 84 to 85 percent. We have been discussing how to get more realistic approval rates.

Question: Why do you think these skewed scores are occurring? Is it an expression of the pressure people feel because of tight funding?

NIH Response: That is one reason. One possible alternative would be to adopt the National Science Foundation convention of funding and declining to fund without reference to approval or disapproval.

Comment: I think that there is a certain amount of pressure on the review group becaue of the competition. Members recognize the pressures on the investigator to have approved applications; they seem to be reluctant to disapprove applications because, in the arguements I have heard, most applications have some aspects that merit approval.

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Question: Isn't it possible that the applications are superior to what they were in the past?

NIH Response: That could be true.

Comment: Another reason is that review groups think that for applications to be funded, they must have extremely good scores. Also, whether applications are funded depends to some extent more on the Institute to which they are assigned than to anything the group does. So rather than disapproving an application, the members give it a 3.5 or a 4.0, which is the same thing as disapproving it, although a little gentler to the applicant. I am not sure that is correct, but that is what they believe.

Comment: The quality of biomedical research in the few areas that I am competent to judge has greatly improved in the United States during the history of the NIH. I know famous professors of physiology in the late 1960's who were using techniques that are still being used, but whose applications would be getting 400's today. They received very high priority scores then in areas that are still fertile. In my area, the people who do incompetent work have been selected against and aren't in the population. I agree that there is a problem, but I think that part of the problem is the wage of success.

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NIH Comment: We have occasionally considered reducing the level of resolution in the priority scores. That is, your result now is presented as a three digit number. Few of us have any real belief that the third digit has a great deal of meaning; and yet, we find ourselves increasingly making funding decisions based on that third digit, as though a 185 is truly different from a 181.

In the future we will need to consider ways to express that priority score judgment differently, so that we preserve a level of resolution that makes sense and does not offer a false accuracy or precision to the number.

Comment: What might help is some stability to the funding lines. One of the reasons that we vote priorities as we do is that we want to be certain that certain applications are funded. So, we give them top priority scores, and they bunch together there; others will be put far away because it doesn't matter so much, as has already been stated, whether they are approved with a poor score or disapproved.

If we had more certain knowledge of the payline, I think there would be a little more differential. We would then be willing to rate a 1.8 instead of a 1.3 or 1.2. Until you can provide that sort of information, I am not sure anything will happen.

Comment: I have also been uncomfortable with the way the priority score is obtained, specifically with the second decimal point in ratings.

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A scientific review group has about 17 members. From this group, for each application you have a primary reviewer, a secondary reviewer, and sometimes a third reviewer. So, from a group of 17 people, only 2 or 3 people have been assigned the responsibility for reading, evaluating, and presenting information on an application. These individuals are usually the only ones who have been privy to the supplementary material, such as reprints and appendicies.

When an application has been presented by 2 or 3 individuals to the entire group, the votes of people who have probably not carefully read the application, which may be totally out of their field, carry the same weight as those of the people who have thoroughly evaluated the application.

I wonder if this isn't one of the sources for the difficulty in assigning a second decimal point. For example, we have all been through this problem in the academic world, where the competition for admission to professional schools is so intense that this practically ruined the whole grading system for our institutions. Institutions tried to avoid giving a student an 89 to a 90, which might be between an A and a B, especially on an essay test.

Some academic institutions responded by trying a pass or fail system that satisfied no one, and the quality of the entire grading process is now in great jeopardy.

Grant applications are also essays, and sometimes a person's whole future depends on the difference between a 1.2 and a 1.8. This is often an arbitrary kind of decision.

I feel the problem lies more in the rating process of the application, than in voting a fundable score. If we could address the issue of how the priority score could be made more equitable, we might have a better opportunity to remedy this problem.

Comment: We tell a member to assign a rating of 1.0, 1.1, 1.2, and so on up to 5.0. A 50 point scale is enough to provide the discrimination that we need. But the problem comes, as was stated a while ago, when we have a 1.75 versus a 1.72 application. To discriminate between those two is still a fallacy even with that many points on our scale.

Comment: Actually, when you base anything on two digits and publish it as three digits, this would be true.

Comment: What concerns me is that one or two people voting high for whatever reason can really do a proposal in. I suggested a few years ago that you knock off the highest and lowest rating to prevent that kind of bias. Although this suggestion has always been turned down on the basis of that every vote must count, I don't think each vote is as important as the distribution and the decimal.

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A committee ought to take another look at all of this, because we are dealing with statistically insignificant numbers, and a person's whole career is at stake based on a third decimal point, which doesn't really exist in the voting scale.

Comment: The problem is one of rank ordering. Whether you expand your scale or make it rougher, somebody has to make a discrimination. For example, you may have a whole bucket of people with 1.8. So, if it doesn't go by the luck of the draw, which is the way it is now whether you are 181 or 182, then somebody else is going to have to make discriminations.

That throws it to the program staff to decide, and I am not sure we are arguing for a better system. Certainly if we think we could convince somebody that we are better than the person whose score is one point better and could get funded, we might like this; but I am not sure that this would achieve the goal of the system.

Comment: With respect to deleting extreme scores, when I was sitting on the Admissions Committee at Johns Hopkins, we had that same problem. Each application went to four or five reviewers on the average, and one person who felt strongly either in favor or against an applicant could decide the person's fate.

As Chairperson of that Committee, I asked a statistician to look into that problem, and he suggested using the median instead of the mean. The median had the advantage that if you ranked scores in ascending order, from, say, 1.0 to 5.0, you then took the mid value. But subsequently we found that some people would be admitted according to the mean but not according to the median. So it was not a perfect solution.

But it is unfair that one individual can essentially kill an application. My suggestion is to enlist the help of a statistician in one of the scientific review groups to try to do something.

Comment: I agree with both suggestions. A feasible solution to this problem may be some combination of considerations as a means of arriving at priority scores. Certainly when we talk about the democratic process in voting, that each vote must count, we are also talking about the meaning of numbers. With that in mind, statistical considerations must come into play, which fits well with the last statement that was made. A way to go may be to look at a combination of considerations, the median plus mean, rather than one as opposed to another. The individual who makes the funding decisions may want to look at both, if that information is available. The possibility of throwing out numbers that are out of the normal distribution pattern ought to be reconsidered.

Comment: I am skeptical that any fooling around with the numbers will fundamentally change anything, because groups will always find a way to make their feelings known. Only one system would

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really change the present situation, and that is if you made everybody simply rank in order, from best to worst, the particular crop of applications. That forces you not to use a number, but to express preferences. While not perfect, this gets you away from the numbering system.

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Question: The cause of the inflation of priority scores has been the abolition of normalization and the competition between scientific review groups to get a few projects funded. We now have groups saying, "We wonder what is going to be fundable this time. Let's get a few people in that window." What is the logic for dropping normalization?

NIH Response: When the decision was made to discontinue the normalization practice, we knew very well that there would be behavioral accommodations by the scientific review groups. We knew that we would have second and third order problems to deal with within the peer review sytem itself and within the funding Institutes in how they use the priority scores. We took that decision with our eyes open.

You may then ask what we thought we were seeing. The primary objection to normalization was that we could not accept the scientific assumption upon which it rested, that is, that there is a bell-shaped distribution of quality in every field, at any time. We didn't believe that; and, therefore, we did not want to consign the NIH for the foreseeable future to erecting further policies on that quicksand. We just don't believe that assumption is scientifically accurate.

Of course, the other path is not the road to salvation either, for it creates a kind of dynamic within the system. But we chose to accept that challenge; and this meeting as well as others like it are attempts to handle that challenge and find some ways to prevent the gaming. If we can't prevent the gaming, then we will find other ways to gather ratings and record them in such a way that the integrity of peer review is not brought into question.

Simultaneously, we need to continue dealing with some funding Institutes who, although they have never been told they had to fund blindly on priority score numbers, have done something close to that because of their respect for the peer review process. Their respect is being eroded by what they see as gaming in the process.

Question: Are the assertions that were raised true? Is the mean priority score rising?

NIH Response: Yes.

Question: And are the distributions now bimodal?

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NIH Response: The distributions are not yet bimodal, but the curve is flattening out, moving towards the extremes and away from the mean.

Comment: In our review group, the gaming that you are talking about does not go on. It is not a question of people not being willing, under some circumstances, to do such things, or being holier than thou; rather, gaming is not operationally possible. We have a large number of ad hoc reviewers at all times; we have an Executive Secretary who interrupts conversations that would go any way in that direction; and we have a tradition whereby we feel that we have to preserve some integrity for ourselves. So for at least one group, I can assure you, that such games have not happened.

Now what has happened in our area, which is a direct result of the propogation of knowledge from related areas, is a tremendous change in quality of applications we receive. Many areas of the field of physiology that 25 years ago and even recently were fundamentally descriptive are on the verge of being molecular, and there is a tremendous change in the quality of the science. The assumption that the quality is on a normal curve will miss the whole point of what is happening in our field.

So for us, the removal of normalization has improved things. And I should just add that if you have a normal distribution on which you apply natural selection, you get something which is very non-normal. In fact, depending on which school of evolution you take, you could get a new species or a new phylum. I would argue that the history of the last 10 years has been a natural selection process producing better quality applications.

Comment: Dropping normalization, as it was previously practiced, was one of the best decisions that has been made in quite some time. If study sections judiciously remind themselves to vote in terms of the full scale, many of these problems that we are now hashing over will evaporate.

Question: The assumption in not pursuing normalization was that one is reviewing primarily science at a scientific review group meeting. But I believe, as some of the questions have brought out, that the system is under a degree of stress, primarily financial, and that the review not only involves the application but also a certain amount of human behavior. In the process of reviewing the applicability of normalization, have the Institutes examined whether certain review groups have few or no applications paid at a particular council because they are particularly tough or don't really understand the grading system?

NIH Response: We have, over the years, spot checked the scientific review groups in this respect. There is a wide spectrum of behavior among the groups, with traditions carried back many years in a particular group. I don't think we have seen a situation where a scientific review group didn't get an application paid, but they have behaved quite differently.

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NIH Response: Your point is well taken that both individual and group behavior are at issue. In making the decision to eschew normalization, we were not denying the behavior element. Instead we were forcing the issue out there so that we could cope with it, as revealed in these various data collections that the Division of Research Grants is now doing.

3. Budgets

a. Direct Costs

Question: Has the funding changed in terms of principal investigators' salaries on grants, and has that influenced the distribution of money?

NIH Response: I am not aware of any obvious change. As you know, our policy has been to accept the rate structures of the applicant institutions and to say that, within reason, we will reimburse whatever percentage of time and energy is judged by peer reviewers to be appropriate to the task at hand. From time to time that logic has been questioned, with suggestions that perhaps we ought to cap those reimbursements in various ways. We have tried to avoid that for the obvious reasons. But I am not aware of any significant trends.

NIH Response: The proportion of funds going to salaries and wages has remained extraordinarily constant over the years.

Question: Isn't there an increase in the number of institutions that are asking even tenured investigators to recover the portion of their salaries represented by their grant efforts?

NIH Response: Yes, that phenomenon has begun, and I think we will see more of this practice.

b. Indirect Costs

Comment: Many of us, particularly those from private universities, feel uneasy about the conflicts likely to arise over the NIH attempt to reduce the indirect cost rates on research grants.* Administrators may simply shift what will be assigned as direct costs to research grants. While we can deal with this administratively, it will lead to a confrontation between faculty and administration.

How NIH got embroiled in this, most of us don't quite understand, and we don't understand why private and public institutions are treated differently, especially since where we end up doing research is somewhat beyond our control. If we are at a private institution, we may be told to place all our salary on the grant; at a public institution, it may be 10 or 20 percent.

* The 1983 fiscal year budget calls for a 10 percent, across-the-board reduction in indirect cost payments for grants.

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NIH Response: The NIH got involved in the indirect cost question as a manifestation of a policy over the last several decades, where the intent not only on the part of the NIH but of the Government overall was to be as flexible as possible in support of funding and to allow for reimbursement of all authorized costs. Therefore, direct as opposed to indirect costs were largely a matter of accounting convenience for a particular project.

The reason the NIH is embroiled now more than at any other time is that since 1966, the percentage of indirect costs in the total grants budget has been increasing. Indirect costs are currently about 30 percent of all of the funds that we award for grants.

We have been working with a subcommittee of the Director's Advisory Committee on the broad topic of the costs of biomedical research and particularly alternatives to containing, or otherwise dealing with, indirect costs.

As you can probably guess, we found little consensus among the individuals on that group. Those who are primarily laboratory or clinical investigators had a skeptical view about either the size of the indirect cost pool or its relationship to the research that they do. The university administrators who participated in that process had no doubts that these were real costs of research, and that the quality of the environment for research would be affected materially should there be any substantial change in the levels of reimbursement. The members of the public weren't so sure. Not having a good way to relate to indirect costs, they generally felt that if the faculty members, who are living in this environment, were not sure about the issue, then they could not be expected to fully understand it.

In the 1983 budget request that was put together within the constraints that Dr. Malone described, it became clear that the NIH could no longer be silent in terms of finding some way to arrest the differential growth of that component of our awards. But I believe you are right that the possibility exists for confrontations of all sorts. There will certainly be confrontations directed against the NIH.

Our rationale is that while there inevitably will be attempts to shift costs from the indirect to the direct cost pool, two major filters stand in that path now. The first filter is the faculty, who in the end are the principal investigators of applications. They will have some influence over what is requested and with what priority.

The second filter is peer review. I am frequently the apologist for indirect costs, which I believe are real. I do not think there is a ripoff going on. But what concerns me is that the level of rigor and external evaluation that is applied to the direct cost budget is not applied to indirect costs.

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We feel that in the short-run, we must take the steps that are indicated in the 1983 budget proposal to arrest the trend. But that only sets the stage for a much more painstaking set of re-examinations and negotiations as to what indirect costs should be, what the Federal responsibility for them should be, and how the institutional administrative practices should possibly change to provide for a broader involvement of faculty and others in that process. I have no way to predict what the outcome will be.

Comment: Having the allocation of indirect costs within an institution known to the chairpersons of the departments would do a great deal of good. A set of guidelines about what is happening with indirect costs might make an enormous difference. It certainly would prevent the fairly common occurrence, according to gossip, of the direct transfer of funds from indirect costs to non health-related costs.

Comment: These kinds of indirect costs, if they are spent on the workings of a university, allow a university to have some funds to deal with emergency situations, such as when your grant does not come through.

Now, some universities are better at this than others, but in the end that is where they get this kind of money to deal with these problems. All we are doing is shuffling the money around into some other format, but in the end it doesn't seem, to me, to materially produce anything new.

Comment: There is at least one institution where I can tell you, in excruciating detail, more than you would ever want to know about indirect costs. I can go over the entire institution and tell you dollar per square foot on any of the departments. In fact, the biggest problem for private universities like ours is that the research costs of most basic science departments are subsidized. It is a rare basic science department that can meet its cost per square foot of maintenance, and I do, in fact, have my figures with me.

It is important to realize that institutions have to take very seriously their indirect costs, because they are frequently audited.

Of course there are problems. But NIH has to look into all of the research. I think there is nothing more frivolous than running a multi-million dollar business of management the way we currently utilize resources and equipment. The NIH permits investigators to keep all chemicals, even if not used, all equipment, even if mothballed, with marginal sharing. We should bring to the investigators the role of management of our resources, especially now that we have diminishing resources. The problem facing us is how to best use our scarce resources and to look toward better management systems. Discussions like this should focus on dealing with such problems.

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4. Rebuttals to Project Site Visits Before the Scientific Review Group Meeting

Question: The Privacy Act now makes it possible for applicants who are site visited to receive the site visit reports prior to the time of the review group meeting. Our group has received rebuttals to the site visit prior to the time of the meeting. We are concerned about this both because the rebuttal complicates the work of the group in trying to make its initial judgment, and also because it may set up situations of unfair advantages based on the time of the visit. It is much easier to rebut an early than a late site visit. I wonder if this problem has come to the attention of other people and how the NIH reacts to it?

NIH Question: The representatives from the funding Institutes might want to speak to this, but before they do, are there strong feelings within the review groups as to how you would like to see those rebuttals handled?

Comment: We feel that this situation is intrinsically unfair. If the site visit report is already known and there is a variance between that and the group's review statement, the investigators wonder what has happened in the review group. We would prefer not to be put in a position of having to defend the initial site visit report before the group formally meets and reviews it.

NIH Response: We have met with this situation a number of times during this past year. Our practice has been to get in touch with the Chairperson as soon as we receive the rebuttal and to bring the material to the review group. In some instances, the rebuttals and additional information sent to the group are more than what is in the application.

Applicants will rewrite entire protocols. Sometimes we receive such material only 2 or 3 days before the meeting.

The scientific review group has, on each occasion, taken the additonal communication and handled it on an individual basis. But these additional responsibilities facing the group in a very short period of time also raise the question of equality for all of the applications being reviewed, since one or two applicants might have the advantage over others because we did the site visit early.

Comment: When such a situation occurs, if there is a large amount of material, the appropriate thing to do in fairness to everyone else is to defer action on the application. Of course, it is difficult to set absolute limits as to what constitutes too much material; but if the application is rewritten in a fundamental way so that the report of the site visit team is no longer pertinent, if the entire group has not had a chance to review it, and if the applicant happens to have been site visited earlier whereas the bulk of the people have not, then deferral is the only fair way to handle that situation.

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Question: Our reports barely get completed by the time of our meeting. How can applicants get reports so soon?

NIH Response: We frequently know we are going to have a request for the site visit report practically before the team leaves the site. So, we are set up here when the Executive Secretary comes back, and our report is done within a week's time.

Comment: We have had requests for site visit reports, but so far we haven't had any problems. We do not site visit every institution that submits an application, but we generally site visit new ones. Of course, the ones that were site visited and rebutted have an advantage over those who submitted in the usual way and were not site visited. But we haven't had any major problems.

Comment: A problem that we have experienced is with applications that are site visited late in the cycle. We occasionally get rebuttals the day of the review group meeting, which presents a different type of problem and is a great annoyance to our members.

NIH Response: In dealing with our constituency, we attempt to make them aware of the fact that under the Privacy Act, they can have access to the system of records pertaining to review of their particular application. As we receive rebuttal materials of a scientific nature prior to the meeting of a scientific review group, we take the information to the group; however, if we have a scientific rebuttal during or after the group's meeting, we use the deferral mechanism. This is our attempt to be responsive to the constituency, and it helps us avoid problems with inaccurate representation of the facts relative to a particular summary statement.

Comment: Most rebuttals we deal with are clarifications of the originally developed application, not a rewrite of the application. When an applicant, in fact, is rewriting the application, then it is incumbent upon us to encourage the applicant to resubmit that application.

NIH Response: The Privacy and Freedom of Information Acts have introduced cumbersome situations into the peer review system, and this is one of several.

We have made various inquiries of our legal staff about what we might do in these situations. For example, we proposed supplying applicants with all the information about the review of their applications but only after the councils had acted. This would treat everybody the same, which has a certain attractiveness about it in that the process would have been completed. But our legal staff said we couldn't do that. As long as we have something in our possession, under the Privacy Act, if someone demands it, we have to deliver.

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We then tried another approach and said that, in the interest of fairness and orderliness, we would establish a standard period of time after a site visit occurred or a scientific review group met. But that didn't work either.

We are aware of the problem and sensitive to it. We have tried to find a way out of the quandry, but so far have not been successful.

NIH Response: Our goal is to accommodate people while also being fair in our attempts to handle information. Frequently, this leads to the appearance, if not the fact, of the kind of unequal treatment that several of you have raised concerns about.

We have an internal forum of senior NIH staff who are concerned with the peer review process, and we have used that forum to follow up on particular issues brought up at previous meetings. I propose to take the specific problem raised here to this forum to see if we can develop better guidances for the scientific review groups, staff and applicants. Whatever we decide on will be far from perfect, given the complexity of the situation and the limits of the law, but perhaps we can find a little more orderly way for handling this kind of information.

5. Review of Fellowship Applications

Comment: This regards the review of fellowship applications from M.D. candidates. Out of a total of approximately 110 applications that we reviewed last round, 10 were submitted by M.D.'s -- something under 10 percent. At the same time, we were given instructions that are the equivalent of a new way of looking at M.D. applications.

Specifically, applications from M.D.'s who are presumed not to have, or indicated that they had no, previous experience in basic research were to be judged more like those from predoctoral candidates. The assumption is that, for at least the first year, the candidate would spend a fair amount of time taking formal courses and becoming familiar with some of the basic research techniques.

There was a general feeling of uneasiness on the part of the members of the group. If such candidates are to be judged on different criteria from postdoctoral fellowships, perhaps we should call them something else. We would like to see a more refined definition of the criteria for judging the M.D. versus the Ph.D candidates. Otherwise, we are in a rather queasy position of not quite really knowing how to make the judgment. We are not sure what we are doing or why we are doing it.

NIH Response: In our discussions with some members of the Division of Research Grants and other NIH Bureaus, Institutes, and Divisions, they have been concerned that a number of individuals with an M.D. were not being adequately reviewed by the fellowship groups.

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In response, we have tried to have more physicians on the scientific review groups to explain to the other members the types of activities these individuals would be involved in. But we are also planning to develop clearer review guidelines. We aren't yet ready to put something down on paper. It needs more discussion among staff.

NIH Question: Do you have some concern about the principle, that is viewing these individuals more as predocs than as traditional postdocs?

Comment: The general consensus of our group is that in the traditional sense, these M.D. candidates are not postdocs. With respect to what they seek to achieve in the 1 or 2 years, they simply don't start at the same place that the traditional postdocs do. Also the ultimate aims or goals of these candidates are clearly not the same as postdoctoral candidates.

Most of us don't really know what species we are dealing with, which makes us uneasy about our overall assessment of the value of the application. This view is also held by the three or four M.D.'s on our review group.

NIH Question: Did you feel that there was a lack of equity, that you were not treating people fairly?

Comment: No. As a matter of fact, the general tendency among our members is to be as ultrafair as we possibly can. But we are not really sure on what basis we should evaluate the applications.

Comment: We met last week. About 35 of the 108 applications were from M.D.'s, and we were asked to review these together. We had a long discussion when we finished, and the group thought this was a good idea.

In these fellowship applications, we are looking for M.D. candidates who are going to go into research and whose training will enable them to have a competitive career when they are through. And one of the major problems with the M.D. candidates is that the sponsors don't know what is going on much of the time. Many of the candidates are using fellowships to continue a final year of their residency program. They are staying in the same place, and when they get through, they will not be trained to carry out research of any kind.

When we see an M.D. candidate who really wants to learn research techniques and will spend 2 or 3 years in obtaining a good basic research background, we have no problems. We want to match the candidates with the research training, and the project becomes less important than the person. And we do this with Ph.D. candidates as well.

But the research project of the M.D. candidate is often inferior to that of the Ph.D. candidate, who has already had considerable research training.

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We need data showing how review groups vote on M.D. versus Ph.D. candidates, but we have to rule out those who are going for 1 year in the same department. If you pull those candidates out of the system, and consider only those who are going for 2 or 3 years, other than in the clinical department in which they are already trained, I think you would be surprised at the very good priority scores they are getting.

The problem is we don't have many of these candidates. For an M.D. candidate, the idea of moving from one university to another is a very serious venture. Many have wives and children, and the stipend isn't high enough to compensate for that kind of move. So, we are looking at a sociological as well as a training problem.

Comment: We have just gone through the same kind of exercise. Roughly a third of our applications are for clinical fellowships; these are submitted by residents in ophthalmology for an additional 1 or 2 years of what is referred to as a clinical fellowship.

These people are forced to invent some sort of research to justify the application, and the quality of the applications is virtually uniformly inferior to the others from a scientific standpoint. Even though we review the M.D. candidates first, we still are forced to apply a yardstick, a scientific value to the research proposed.

But we are under great pressure from our clinical colleagues to give better priorities to these clinical fellowships.

I don't think this problem is reconcilable. I don't think that it is wise for a scientific review group to give a fair review to a group of basic science proposals, requiring high degrees of scientific exactness and accuracy in the proposals, and then immediately turn to a bunch of poor applications. The clinical applications suffer.

Our group feels that we should have separate reviews for these two types of applications.

Comment: The need for special competence in some area has created a problem; because even though an M.D. might be interested in research, after having taken a residency, the candidate wants to use the fellowship to further a special competence in an area, such as cardiology, for a 1 or 2 years. I see a trend now of 1 year of basic science research on top of the 2 or 3 years that is required for special competence training. Perhaps we should be more lenient in providing that kind of research training rather than an extensive fellowship for clinicians.

A clinician trying for a fellowship, without question, has two strikes against him when he submits the application. It is unfair.

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Comment: I don't agree that the clinician who applies has two strikes against him. As I said before, I would like to see the data on the priority scores for Ph.D.'s versus M.D.'s. I think the scientific review groups bend over backwards for the M.D.'s.

But if you fund people who are not going to be competitive, or who have no chance of being competitive when they are finished because of their training background, there is no point in spending that money. No matter what, I still think you have to find candidates who are dedicated, who really want to get into research and spend their time in the training required to be competitive in their field.

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Comment: The fellowship application is too non-specific in its advice to the candidate. The instructions say "Be brief," and we are seeing a range of proposals that vary from a very good research project plan to a three-page bit of nothing. You don't always know whether this is a difference in interpretation by a naive applicant to the words "Be brief." I suggest that the same format for the research project grant applications (form PHS 398) be applied to fellowship applications.

NIH Question: Would you suggest some page limitations?

Comment: Yes.

Comment: Our committee felt precisely the way you do. But the form cannot be the same as the PHS 398, because many fellowship criteria aren't spelled out there.

For example, the PHS 398 does not cover the justification for remaining at the same institution where one received a Ph.D. And remaining at the same institution may be a critical aspect of our ultimate evaluation. The candidate may be great, the project fine, and the lab excellent, but it may be next door to where he or she took a Ph.D. It might be relevant if there were some statement in the application that indicated the obvious advantages for a person to take a fellowship elsewhere. As it stands now, there is only a statement that says to justify remaining at the same institution; yet, the candidate, in a critical way, has to justify staying at the same institution.

Another problem we see is the relative homogeneity of the average scores that candidates receive in reference letters. Although it is probably true that only the unusually bright doctoral students are encouraged to apply, there is still a problem in discriminating among candidates. For our September 1981 meeting, the average ratings in the reference letters for each category were as follows: originality, 1.6; accuracy, 1.4; research ability, 1.4; scientific background, 1.5; and ideas, 1.5. The overall average was 1.44;

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19 percent of all candidates had averages less than 1.2, 44 percent less than 1.4, 72 percent less than 1.6, and 91 percent less than 1.8. We had to make decisions between a 1.2 and a 1.8, which were really not meaningful.

Perhaps we should have a 1 to 5 range, but assign each number a different significance. For example, 1 would be truly outstanding, the best in several years; 2 would be definitely superior, one of the best in a given year; 3 would be clearly above average, the top 25 percent in a given year; 4 would be above average; and 5 would be average or below. This would make more sense, at least as far as I am concerned, because the general feeling is that people getting 2.0 or 1.8 are not likely to get funded.

Otherwise, the curve is extraordinarily skewed and the difference between the funded and the not-funded is very small and doesn't really make much sense.

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Question: How strongly does the NIH feel about someone taking postdoctoral training in a foreign country versus training in the United States?

NIH Response: I don't think there is any easy answer to that question. My sense is that as competition has become more severe, more national advisory councils and NIH staff members have been questioning whether foreign training is absolutely essential or a unique situation. I expect that attitude to continue. People will continue to examine very carefully any plan to take part of one's training in a foreign laboratory.

Question: If, for example, the opportunities in a foreign land and in this country are at least equal, must a candidate make a perfect case for taking the training in a foreign country?

NIH Response: The NIH, to the best of my knowledge, has not provided any directive quite that specific. What we have been seeing in both the Institutes and the review groups is a move in the direction of looking for more than simple equivalents, for some special advantage for the foreign training.

Comment: Our view has been that the candidate must make a very strong case to justify foreign training.

NIH Response: A number of national advisory councils have been questioning whether we should continue to support any training abroad. That is another part of the problem. But as far as the scientific review groups and the candidate are concerned, the candidate must strongly justify any proposed foreign training.

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Question: What is the funding rate for postdoctoral fellowships?

NIH Response: About 40 percent of those applications recommended for approval.

Question: What is the figure for all fellowship applications?

NIH Response: Probably not much lower, because fellowships have a very low disapproval rate. I would say about 30 or 35 percent.

Comment: I don't think it would hurt to publicize more widely those percentages, because a common rumor in the field is that the fellowship application funding rate is very low. Students feel that NIH is not funding fellowship applications any more. We have got to turn that around. Perhaps we need some form of letter to the research communities.

6. Review of Research Career Development Award (RCDA) Applications

Question: Many members see the RCDA as an award for excellence, whereas others see this as a mechanism for changing the way a particular school apportions an investigator's time. There is a discrepancy in how RCDAs are reviewed from one review group to another. What are your feelings about the relative merits of those two positions?

NIH Response: If you have had a chance to look at the proceedings of these meetings for the last several years, you will find this has been a recurring topic of discussion. The RCDA is a classic example of a mechanism that made sense a long time ago but has been overtaken by events and changing attitudes. The NIH will have to come to grips with exactly what it wants that award to be and make that communication clearly.

As it stands now, there are almost as many different perceptions about how the RCDA should be used as there are Institutes. Attitudes range from a few who believe the RCDA to be an integral part of their program to one or two others who use it rarely, if at all. Then there is a group in the middle, who think of it more as a prize, as a designator of the next generation of truly productive individuals.

The only guidance that I believe we can offer you in the short run is to view the RCDA as an award to encourage the maturation of individuals as independent scientists, from a point where in their careers it appears as though they have considerable promise to a point where they might be numbered among the most productive individuals in their particular fields. The award was to provide the lion's share, if not all, of an individual's salary, and thereby free him or her from the other demands and pressures that are characteristic of an academic institution.

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I know many academicians who believe this to be a mistake, one that isolates these individuals from the main fabric of their institutions. I would ask only in your review that you not make separate policy, because that is potentially injurious to the applicants and frustrating to the Institutes. If you have doubts about the attitudes of a particular funding Institute for which your group may review a large number of RCDA applications, I urge you to invite Institute representatives to the meeting to explain their expectations and attitudes, so that you are not spinning your wheels.

It is hard for me to believe that the NIH will go through many more years with the RCDA in its present form because of the mixed signals we are giving and the frustrations for the review groups and for our own funding components.

NIH Response: The review of RCDA applications has been a considerable problem for the Division of Research Grants. Even though we have guidelines for the review of these applications which were updated last year, as were the application instructions, different scientific review groups seem to be applying their own review criteria. We continually remind the Executive Secretaries to be sure their groups use the Division's guidelines and not establish their own criteria.

Comment: I read through last year's discussion, and I would strongly echo a view alluded to there. I am opposed to the puristic view of the RCDA held by some groups, that candidates who include some moderate participation in departmental or institutional responsibilities thereby compromise their research development. This unfairly penalizes RCDA candidates. It isolates them totally from the academic community in which they are to develop research potential. It gives candidates, in my judgment, a totally wrong and inflated idea about the exclusivity, the ivory tower nature of research. I wish we would return to the "good old days" when it was perfectly acceptable for RCDA recipients to spend, let us say, 10 percent of their time in teaching.

NIH Response: The National Institute of General Medical Sciences probably feels more strongly than most that the RCDA is a mechanism that, from our point of view, has outlived its usefulness. Based on a number of considerations, no situation has caused more problems for the National Advisory General Medical Sciences Council for the last 8 years than has the RCDA.

First, each individual scientific review group has been essentially setting up its own guidelines about what is development. Is it an associate professor? Is it an assistant professor? Is it 20 papers? Is it 30 papers? Is it the ability to get a research grant?

Second, as a salary mechanism, if a research project grant is not awarded to the RCDA recipient what happens? Do the individuals really get the research done that we all want them to do?

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Third, inherent in the RCDA mechanism has been an institutional commitment to an individual, and I agree with the last speaker that although there is release time, no one ever expected it to be 100 percent of the time. But when it is a research foundation or an institution that is not a teaching institution, what can the NIH do for this individual with an RCDA that cannot be done without the RCDA?

So, our Institute came to the conclusion that for the basic science areas we support, there should not be the RCDA mechanism. If individuals are spending 90 or 100 percent of their time on research, we would like to pay for that under the research project grant mechanism. The only area where we find the RCDA to be important is in bridging the gap between basic and clinical research by enticing individuals to move from basic into clinical research.

Comment: As an observer of the NIH and the Veterans Administration systems for a number of years, I have noticed a great deal of pride in the Veterans Administration program. That pride emanates from the fact that there are clear-cut guidelines for the various levels of career development within the program. They made distinct separations between research commitments and administrative or teaching commitments. I encourage the NIH to look closely at that program in the development of a new set of guidelines for the RCDA.

Comment: This discussion has focused on an important aspect, that the various Institutes have different priorities. The Clinical Research Centers Branch,* concerned over the vanishing breed of clinical investigators, has established a program that is similar to the RCDA, but nonetheless special and specific. With the Clinical Associate Physician Program, we encourage investigators who are possibly trained in the basic sciences or at the end of their fellowship training to develop as clinical investigators. Because this area is more narrowly defined than the RCDA, it has, I think, been more uniformly evaluated.

The NIH may not be able to establish one development mechanism or uniform criteria. Different Institutes have different needs and must define their own programs. Some Institutes may not even need RCDAs.

Comment: I am concerned about abolishing the RCDA because of the many outstanding scientists who have been recipients of the RCDA. If the intention is to do away with the RCDA, it seems to me that we certainly should have some other substitute in order to encourage clinical investigators to enter research or to help other developing researchers.

* Division of Research Resources

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NIH Response: There certainly is no plan to abolish the RCDA. Many of the Institutes feel strongly that they need this instrument or something very much like it, and would therefore be strongly opposed to any central NIH decision that the mechanism not exist.

In addition to the RCDA, we have a variety of academic investigator and clinical investigator awards. These are really people-oriented awards and deliberately so. A frequent criticism directed toward the NIH is that we are much too concerned, at least nominally, with the projects that we fund and not enough concerned with the people. It is easy for our colleagues and for me to point to the law when the law talks about projects, about particular quanta of science that are to be carried out; and yet all of you know very well that a major part of the assessment of an application is the quality and the potential for productivity of a particular individual.

Therefore, part of the examination of the RCDA must be the larger question of whether we can make overt provision for some kind of people-oriented award. It may be a one-time award, as with the ones mentioned, or perhaps renewable indefinitely, which is something we have never done but is potentially worthy of consideration. These are the kinds of considerations that will have to be worked through cooperatively by all of the NIH Institutes before we can give you definite signals about how to carry out these reviews most effectively.

Comment: It is important that the NIH continue to support people as well as grants, because developing scientists constantly come up with new approaches. If we retreat to the thought that we are just interested in the grant rather than the person, particularly a young person, something is going to be lost.

We are all worried about encouraging young people with M.D. or Ph.D. degrees into biomedical research, when they can find other more lucrative opportunities. We can deal with the concerns that come up by making the definition for their support a reasonable one, a logical one, one that will further their development not discourage or retard it. We must eliminate some of the ambiguities in the current program.

7. Review of Applications from Members of Scientific Review Groups

Question: Could you explain more clearly whether the studies you did from 1975 to 1979 are pertinent today? (For a summary of these studies, see Appendix B.)

NIH Response: Let me give you a capsule discussion of what we found, with the caveat that it needs updating, for we are obviously in a different climate. First the people we select for our study sections* on the whole do better than the general population. Obviously, we try to get experts, and one mark of an expert in a

* Scientific review groups in the Division of Research Grants

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particular field is a better priority score, a better approval rate. So, we are dealing with a population that gets better than average priority scores and better than average approval rates.

We took, however, for the purposes of this study, people who constituted the members of DRG's study sections in 1977. Then we looked at all of the applications that population had sent to us between the years 1975 and 1979. Since the population on the study sections consisted of people serving in the first, second, third, and fourth years on each study section, we had applications coming from this population before service on study sections, coincident with service on the study sections, and after service on the study sections.

One of the concerns was also whether it made any difference if an application was reviewed by an ad hoc group, by a Special Study Section, or by another existing study section.

To summarize, applications from people before they came on study sections, while they were serving on study sections, and after leaving study sections, all fared about the same. Also, there was little difference if we sent an application to the same study section, which we could legally do only before or after service on a study section. Among the three groups, there was essentially no difference in where we sent their application for review.

I cannot see any disadvantage that you incur from serving on a study section. We are updating the study, but from the statistics thus far, you do not seem to be hurt in any way by serving on a study section.

B. OTHER ISSUES

1. Quality of Peer Review

Question: I know the issue of the quality of peer review is very difficult to evaluate, but I have heard some recent concerns by people about this problem. There is a general feeling among people who have been on study sections that while this is a tremendous experience, it is something they don't want to do again. As the years have gone by, since we cannot go back to this group of people, has there been any depletion of quality? Is this a real problem and, if so, how has the NIH staff dealt with this?

NIH Response: You have asked something that is almost solely subjective. I can only give you my opinion. Having been an observer of and co-worker in peer review for the better part of the last 16 years, I see no perceptible dimunition in the quality of the people, the energy being brought to the task, or the match-up between their skills and the peer review that needs to be done.

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But I do see some dimunition in the quality of the whole process, largely reflective of the workload to which everyone is subjected. I can remember a time not all that long ago when it was commonplace for everyone not only to have read the applications, but also to have looked up some of the references. During my first year here, I was astounded that one of the peer reviewers had rederived all the equations in a grant application because he thought the original derivations were incorrect. In my experience, I rarely see that happening now. I rarely see anyone having the time or energy for that kind of level of individual critique.

In addition, with the numbers of applications being reviewed at each meeting, my impression is that we fall short of taking full advantage of the group discussion process, the debate to a consensus that has been characteristic of the NIH system. While still very special, the group discussion process falls necessarily short of where it might if the workload were less.

Last, but not least, the Executive Secretaries are left with the enormous burden of trying to distill not only the subject matter but also all the nuances of those discussions. Several members of scientific review groups have raised the concern that the summary statement is often too laden with the draft language written at home by the peer reviewers and not a fully accurate manifestation of the tone of the discussion at the meeting.

We are sensitive to those concerns and are laboring with them. But we are working with a suboptimal overall process because of the workload, almost beyond the control of any of the individuals in the system.

NIH Response: I agree with everything said, but would add one more factor that bears on the problem. In the Division of Research Grants study sections we are currently reviewing about 21,000 competing applications in a year, and the NIH is funding, at best, 5,000. What happens to the morale of the study section members, knowing they are working very hard to get one in four funded? This will inevitably impact on the quality of peer review.

2. Fraud and Abuse

NIH Comment: I would like to outline for discussion the rather unpleasant subject of misconduct in science. We have had a rash of incidents in the last several years that has shaken this establishment and the scientific community to its foundations. These incidents have caused us to treat this as a first-order problem, at least as a threat to public confidence if not as a threat to the fabric of science itself.

I am including under the label of misconduct a variety of things, such as violating the conditions of a grant or contract by failing to protect the rights of human subjects, failing to care adequately for laboratory animals, or failing to follow the guidelines for recombinant DNA research. But this also includes misrepresentation of the results of research, ranging from plagerism, to the biased selection of research results, to the fabrication of data.

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While we have not had many of these cases, only about 9 in over 20,000 applications last year, unfortunately, we have had at least one of everything I have just suggested in the last 3 years. This has caused us a good deal of concern.

At one level, NIH has an array of administrative techniques for dealing with such matters. In theory, if a criminal statute has been violated, such as the knowing provision of false information to the Government, then we have certain mandatory responsibilities to make this known to the Office of the Inspector General and to the Department of Justice. Only those offices can decide whether a criminal prosecution is appropriate in each case.

There are no hard and fast rules. But, in general, to the extent that large amounts of money are involved, especially money going into the pocket of individuals, prosecution is likely. On the other hand, when large amounts of money are not involved, when the malfeasance is more in the science itself, it is likely, though not mandatory, that the Justice Department or the Inspector General will opt not to prosecute. Instead they usually return the case to the agency and ask them to take appropriate steps of an administrative nature.

In that arena, the NIH has a number of options. One is not to make an award if we have any significant questions about the individual or the institution involved. Another option is to suspend or terminate ongoing grants or contracts for cause. Within the last year and a half, there has been introduced a procedure called debarment, which provides due process for an individual or an institution, after a hearing, to be rendered ineligible to be considered for grants in our system. For many years, we have also had an analogous debarment provision for contractors or potential contractors.

Up until about a year or so ago, we were content to rely on a case-by-case handling of any problems. We defended ourselves before the Congress and others with the argument that the number of cases had been so few and so different from one another that we didn't want to codify that into any kind of standard procedure.

We received the well-taken criticism that, notwithstanding our good intentions, in the absence of any explicit procedure, we were subjecting individuals, at the very least, to the risk of inefficiency and delay and, at the very worst, to some violation of their rights to due process. For example, if individuals were accused of fabricating data, we were not informing them about the specific way in which the matter would be handled, nor was it automatically clear at the start what sanctions the agency might consider.

We accepted that criticism. Over the last 6 months, we have been working toward putting into place some kind of conceptual framework that will allow our staff and the institutions with which we deal to understand better the logical flow and procedures whenever we

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are faced with an instance of real or apparent misconduct in science. Within the next several months, we will produce a draft for comments with proposed guidance for our staff, for our applicant and awardee institutions, and indirectly for our advisors as to how we plan to deal in a more formal way with these considerations.

One aspect of this situation that touches on peer review is our recently instituted alert system. For an agency as big as NIH, one problem is making sure that one hand knows what the other is doing. Therefore, when an individual or institution is under formal investigation by one of our units, that individual or institution is identified in our central computer system in a well-controlled file. Should we receive a grant application or contract proposal from that individual or institution, the alert procedure brings this fact to the attention of my office and to the one or more appropriate Institutes. Then we decide about how that application or proposal should be handled.

As a general rule, we have tried not to introduce any of the issues surrounding the investigation into the peer review process, wanting to reserve that on a need-to-know basis for the national advisory councils and for the funding Institutes.

But we are mindful that thse incidents, though few in number, are generally ladened with public interest and publicity. Frequently a review group will meet knowing something about the incident as a result of press coverage or rumor in the scientific community; and therefore, the group will need to have a full disclosure of the facts, as we have them, to ensure that those issues extraneous to the application are dealt with in a reasonable way.

In addition, several cases developed where part of the sanctions against the individual was to recommend to the Director of NIH that the name of that individual be kept in this alert system for 2 or 3 years. Should there be any future grant applications or contract proposals from the individual, these would be accepted by the NIH; but during the review process, the results of the prior inquiries and the sanctions taken against that individual would be made known to the peer reviewers. This was done in a few cases where the nature of the offense, in the judgment of the investigating group, reflected on the individual's capabilities as a scientist. Knowing that peer reviewers place heavy weight on the qualifications of an individual, we felt strongly that the results of the investigation should be shared.

We are a long way from having anything final, and we desperately need the advice of the scientific community, including peer reviewers. I will be glad to react to any comments or questions.

Question: At what point in the proceedings does the individual become aware of the investigation?

NIH Response: When we have started a formal investigation.

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Question: Is the alert established by that time?

NIH Response: First, there may be a phase of information gathering or fact finding. For example, we might receive a letter suggesting that investigator X has been guilty of something. We may have to do some information gathering to understand whether that is a crank letter or whether there is some substance to the issue involved. This is not a formal investigation.

In this search, we rely on two units at the NIH -- the Division of Management Survey and Review, and the Office for the Protection from Research Risks. Depending on the issue, we may ask one or both of those units to follow up on it. They determine whether something warrants a formal investigation. At that stage we trigger this alert system.

The individual is almost invariably aware when something reaches the stage where we begin a formal proceeding of some kind.

Question: How is the individual made aware of it?

NIH Response: In the few cases we have had, the individual has usually been aware of it well before we decided to investigate formally. Sometimes, other colleagues made charges or accusations, and many of those found their way into the media. So, it was a matter of some public attention before we got involved. If there hadn't been any other indication, our group, upon launching an investigation, would have some inquiries to make of the individual or the institution and would represent themselves accordingly.

One of the interesting aspects of this dilemma is that when Dr. Fredrickson and I testified before a Congressional committee, we were soundly criticized for using the phrase "presumption of innocence." That seemed unusual at the time, but later our critics' intentions became clear to me. Strictly speaking, these terms were from the judicial system, and the Congress was saying that in the absence of a set of procedures and practices, we should not use such terms.

We must have an array of administrative actions that, on the one hand, protect the public interest, insuring that money isn't flowing freely for what may be indefinite periods, and, on the other hand, do not judge individuals who have not had an opportunity to defend themselves, so that there is no orderly way of resolving the questions. The Congress wisely didn't try to prescribe a procedure, but was quite clear in its criticism of the absence of any procedure. We have accepted that as fair criticism. We are now trying hard to put something into place that, we hope, will be used very infrequently, but will be as fair and as honest as possible.

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Question: How are you going to self-insure and how are you going to insure us? Are you going to provide the funds that are required to insure scientific review group members being sued for malfeasance, or contributing to the problem that the investigator feels that he is being sued for? I think that is a very real issue. Perhaps not many of you in the Government carry malpractice insurance; but I do, because I ran a diagnostic laboratory for a long time, and administrators, at least in most institutions, need some degree of protection.

Comment: I think that in most circumstances, review and punitive oversight are not comingled in the same group. I would hope this could continue at the level of the scientific review group.

NIH Response: You have given most of the answer to the question. Our intent throughout has been to insulate and isolate the peer review process to the maximum extent possible. A good example of that is our alert system. The way that policy is designed, only in exceptional circumstances would we bring the information to the scientific review group. To the extent we possibly can, we want to have the scientific merit review based only on the application before you.

Of course, as I mentioned, there may be cases involving so much press or other media attention that there was no way you could ignore those factors, and we might then have to provide you with a more fully accurate and complete story.

We expect to continue, as much as we can, to keep these things separate. Nonetheless, there is always at least the theoretical worry, and, as I hear you warning us, it may be a lot more than theoretical.

Employees of the Federal Government generally can expect to have the protection of the Department of Justice insofar as the acts they have carried out have been part of their official duties, and they have not been just grossly negligent in the handling of these acts. We like to believe that our advisors might have similar protection.

NIH Response (Legal Counsel): Your assessment is accurate. The situation with outside advisors is problematic--for one purpose, the regulations expressly state they are not employees; for other purposes, it would be beneficial to view them as employees.

The question has come up in the past, in other contexts, with committees that have been advisory to the NIH, and we brought the question to the Justice Department. We were told that while we could not give a categorical assurance that a particular example would be represented by the Justice Department should there be any lawsuit, they looked favorably on the situation in terms of representing that individual. For they recognized that even though the

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person may not have officially been an employee, he or she was assisting the Government in carrying out its function and, in a sense, performing a quasi-Government function.

NIH Response: In my judgment, the probability of review group members having any significant difficulties in this area is very slight, and we will do everything we can to insure that the different functions are clear, and that those people who have to make the decisions about not funding or other disciplinary actions are the ones who are the clear actors.

Comment: I am worried that the incidents of fraud may be somewhat more than we at present believe. I am in a fellowship review group where we were forced to consider one of these instances recently. In this case, between the time of submission of the application and meeting of the review group, the national press was made aware of the fact that the background research of the program was a fraud. The group was then faced with reviewing an application from a candidate who was personally blameless, but had nevertheless presented a research proposal that was fraudulent. The fellowship group was able to review the proposal and, in fact, recommended approval essentially by ignoring the research. We concentrated on the candidate's background and credentials.

Comment: Most of us in the basic sciences are not surprised. We feel some of the grants are too big and the principal investigators too little involved to supervise the work that is being done. I think it would be naive to assume that just because big groups are productive and cranking out enormous numbers of papers that the work is well done. Everybody has to be suspicious of laboratories producing 100 papers a year. None of us is able to write so many papers in a year and read them carefully.

It would be worthwhile for the NIH to exercise some caution about the size of individual groups that receive funds. This may be unpopular at medical centers, but I think some caution is needed.

Comment: One has to be careful about metastasizing legal fictions. It is a legal fiction, in my opinion, that a man can chair a department of medicine, have two major hospitals, or something of that order, under his control, publish a staggering number of papers a year, and be in reasonable control of what is going on.

The NIH once before, in my experience, got into a situation of supporting a large amount of training work where it was common knowledge that this was being used for supporting residents with straight clinical duties. We paid a terrible price for that and we continue to pay it. I think that you may be dealing with an extremely dangerous issue.

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Comment: Obviously there seems to be some disaffection with the great man theory here. However, there is a relatively simple solution. It used to be said at one well-known university that an undergraduate could do almost anything except pursue a course of moral turpitude with the president's wife or copy someone else's work. This would lead to being asked to leave the institution, and one's name would be expunged from the ledger. This policy was known and generally followed. I know there are complexities in those kinds of situations, but it was a course known to every freshman.

Aside from saying to an individual scientist that we understand the pressures on a scientist who may feel forced to say something other than the truth in order to continue in the world, it would be better if it were well known that cheating on research would be a form of research suicide. A quick, clear course with appropriate punishments might save the day. It would certainly insure the reputation of the NIH.

Comment: I think some cautions should be put on what was stated about big, overwhelming groups not being able to control their own research. You can find certain people who are energetic and can handle a very large group.

Comment: I don't want to be too specific, but I think we all know what is involved in the administration of some medical center departments. I simply do not believe that somebody with those kind of administrative duties can carefully be on top of the number of research projects that produce 20, 30, or 40 papers a year.

Perhaps it is simply because I come from an area of science which is the other extreme, but I would like to see the review process be very tight about this. I think that the examples we are seeing will not be isolated. I share the view that as the press becomes more involved and as people begin looking, you may see a lot of this from the same kinds of areas.

NIH Response: One subject that surely will get more attention from the Congress is the degree to which various individuals who are responsible for funds are also participating directly in the research and co-authoring papers. Much of the criticism of several hearings that we were subject to last year was challenging not the NIH but the practices of various academic departments with respect to the involvement, or noninvolvement, of senior officials. There were not specific accusations other than suggesting that this was an area for further discussion; the Congress wanted to understand better the dynamics of the process.

Comment: I have always been comfortable with the fact that there are many people who can do far more than I can do. I find it difficult to know how to decide whether someone is, or is not, capable of managing another research project. I don't see how that can be practically enforced.

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Comment: This is done every day in the review group. If you see an application where a great man is budgeted for 10 to 12 percent of his time and he has $2,000,000 in grants, you have an idea that the amount of participation is small and he is lending his name for its magnetic affect.

Question: This is also a problem if drug company support is going into a major laboratory. For example, we were talking about the recombinant DNA work. Does such private industry support have to be reported on an NIH application?

NIH Response: On the PHS 398 form, an individual investigator has to report all sources of support that are currently active or pending review or award. But, of course, there is no way of checking something that is not reported.

3. Awards for Small Businesses and For-Profit Organizations

Question: Can you provide some updated information on the Small Business Innovation Development Act of 1981?

NIH Response: Congress has several pieces of proposed legislation under the general heading of the Small Business Innovation Research Act. The purpose of these bills is to ensure a larger fraction of the Federal research and development dollar going to small business organizations. According to one of the advocates, these small businesses will then be able to do a greater degree of commercialization of their product, create additional jobs, and improve the economy.

The Senate bill includes, among other items, a one percent set-aside of the research and development budgets of all agencies spending in excess of $200 million a year, which includes the NIH. This bill had more than 80 sponsors when it was introduced on the floor, and passed the Senate by a vote of 90 to 0. On the House side are three different bills, which are similar to the Senate version and differ primarily in the set-aside.

The legislation that is getting the most attention is an amalgam of those bills, which provides for a 3 percent set-aside of the research and development budget of those agencies that I mentioned.

Originally, the Administration had reservations about all versions of the bill. But within recent months, the President has indicated his endorsement of the Senate version in writing to the sponsor of the legislation, Senator Rudman of New Hampshire.

Should the Senate bill pass, we would then have an obligation to set up some type of set-aside program to ensure that at least one percent of the funds available to us flowed to small businesses for research and development. We expect that the thrust of that will be in the applied research area, for in our experience, few small businesses have approached us wanting to do basic science.

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A major change almost coincidental to this is the decision of the Secretary of the Department of Health and Human Services to open the grant system to for-profit organizations.

The notion of opening the grant system has been under discussion for about 3 years in the wake of another piece of legislation, the Federal Grant and Cooperative Agreement Act. That legislation attempted to redefine the relationship between Federal agencies and the recipients of Federal funds, that is, to set up some conceptual rules for when a contract or a grant would be used.

In brief, the Act says that when the Government is attempting to acquire something for its own benefit and use, this is a procurement and therefore a contract is appropriate. This is true even when the material being sought is the result of research, such as a device or a particular data set. By contrast, when the principle purpose of the agency is to assist or support an individual or an institution in the conduct of something that is at the initiative and direction of that individual or institution, then a grant is the appropriate device.

As that concept was put into law with the ensuing administrative actions, a corollary question arose as to whether the identity of the recipient made any difference. If the primary purpose is to distinguish whether the Government is procuring something or serving as a patron, does the nature of the recipient organization matter?

It became increasingly clear that in most cases it did not make a difference. The Government's intent was to support the grant that was appropriate.

Therefore, the Office of Management and Budget issued a directive to the effect that unless we had legislation proscribing grants to for-profit organizations, or unless we could show that it was somehow contrary to our mission, we should make the grant system open.

We have no legislation proscribing it. Nor could we demonstrate that this would be contrary to our program's purpose. So, we joined our voice to the others within the Department, and ultimately the current Secretary decided to open the grant system.

The decision to open the grant system has been made. But we are still weeks or months away from its final implementation through the changes in our regulations and procedures. The legislation on the small business set-aside will be debated over the coming weeks or months, and neither I nor anyone else can predict with certainty when or if it will emerge, or specifically what form it will take.

Question: The concern of this group is how to handle peer review. Will the peers be competitors or will they be members represented by the panels here?

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NIH Response: We have every intention of using our existing peer review system for this. Of course, we have to revise our conflict of interest guidelines, because things change when you have competitors; but we have no intention of setting up a different system.

Question: In the case of the small business legislation now in Congress, how do they define a small business? Would several faculty members setting up a concern in their spare time qualify as a small business?

NIH Response: I don't have the definition memorized. Through the Small Business Administration, there are standard definitions based on the annual volume of business and/or the number of employees.* But to answer your question, it is highly likely that a group of faculty members, given the indulgence of an institution, could find a way to incorporate themselves.

Question: My question concerns proprietary rights with grants made to for-profit organizations or small businesses. Will companies applying for these have to sign over their rights to patents just as universities do?

NIH Response: Another legislative development during the last year or so has been a set of amendments to the Patent and Trademark Act. The thrust of those amendments is to provide all nonprofit organizations and small business with first rights to the inventions they produce under Federal funding, either through grants or contracts. What that means is that now all nonprofit organizations and small businesses have essentially the same rights as those institutions that had previous institutional patent agreements with the NIH. Before this legislation there were 80 such institutions; now there will be more than 500 nonprofit institutions and an undetermined number of small businesses. This will simplify much of the handling of the proprietary rights.

4. Sliding Scale for Funding

Comment: With the present fiscal reality, it is almost unavoidable to go to some type of sliding scale. As was suggested by one speaker last year, applications might be funded at 100 percent, 80 percent, 60 percent, and so on down the line depending on their priority scores.

The situation has reached a point now where some applicants with a score of 155 are not being funded. In terms of the research productivity of this nation, it is incredibly wasteful to turn down those projects.

* For research and development small businesses, the number of employees must not exceed 500 persons. (See Federal Procurement Regulations, Subpart 1-1.7: Small Business Concerns, Section 1-1.701-1[e]: Research, Development and Testing.)

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The counter argument is usually that we would be underfunding projects. But I think we can look at certain universities and grantees where people are overfunded. We all know grantees who are good at the game of grantsmanship.

We could do a balancing act. I recognize that with a limited staff, it would be difficult for NIH to work this out, but there are many terribly good people in institutions who are hurting. Topnotch people are not being funded.

Comment: I think this is a good idea. An absolute cutoff say between 180 and 181 is ridiculous. You have to institute something in between to give the person at the 181 level some piece of the action. I certainly support a sliding scale concept. I know it is very difficult to do, but it is not impossible.

Question: What are the arguments against the sliding scale?

NIH Response: The principle argument starts with our legislation, which talks specifically about projects. To the extent that one believes that the recommendation of a peer review group is the minimum reasonable amount of money to do that task, it follows that awarding 90 percent, 80 percent, or 70 percent of that amount is funding something that is technically different than what the review group thought it was recommending. Under that reasoning, one is, by definition, underfunding whatever was recommended to the agency.

People are quick to counter by arguing that investigators don't do research this way. People are infinitely flexible in adjusting their circumstances, and most investigators with, for example, a 185 priority score application that was about to go unfunded would happily submit a revised budget at 90 percent of the approved level and tailor the research accordingly. Therefore, the public interest would still be served.

But the principle counter argument has been the concern about consciously underfunding work when our legislation is rather clear to the contrary.

Question: Isn't that the case though when an investigator receives a fine priority score but the budget is trimmed? If the investigator submits an application for $200,000, which is approved with a very good priority score, but only gets $150,000, he or she cuts out some research elements. What is the difference?

NIH Response: The major difference is that when a review group recommends reducing the requested budget, this is generally accompanied with some suggestions about what should be deleted and about how the amount recommended ought to be spent.

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Under the sliding scale concept, the reduction would be an arbitrary fraction. That already reduced budget might be subject to another 10 or 20 percent reduction, not on substance, but rather on where it fell on the priority score scale. Then the Institute funding the research would have to be sure that the residual was still worth funding, that there was still something worthwhile that could be done along the lines of what was originally proposed. That is the dilemma.

Comment: I understand your argument, which was expressed last year too, that the sliding scale concept is in violation of the principle of the project grant. Yet, it seems to me, that even at the expense of perhaps 4 months delay, negotiations could be carried out with the applicant after the priority score has been settled. It could be an amended or adjusted grant application. This is difficult to implement, but I think it would be worth having a whole session devoted to that one question.

NIH Response: Your point is well taken. I wouldn't want to leave you with the impression of being unalterably opposed to a sliding scale. It was easier in the past when there was more money and more flexibility to hold to the original principle of the project grant as expressed in our legislation. With the current funding situation, with people faced with an all or nothing situation right around the payline, we may have to explore new approaches.

Comment: I think all of us around the room appreciate the difficulty of introducing this new way of doing things, but if one wants to be purely logical, it defies science to think that the third decimal place has any meaning. Many of us are proud of the work of our review groups, but I don't believe many people around this room are confident about that third decimal place.

Therefore, I think that the situation calls for finding a way to accommodate what has been proposed.

In terms of its legality, if one wants to renegotiate a budget, I doubt if there are many people who wouldn't have sufficient flexibility to come up with a reduced format for a lesser budget if the alternative were no funding at all.

Comment: This is the practice at the National Science Foundation and the Veterans Administration. Applicants' budgets are sometimes revised downward drastically, but the agencies still find plenty of people to take their money.

Question: Am I to understand that the proposal to use the sliding scale is a consequence of the compression of priority scores?

NIH Response: I believe it is primarily the consequence of the number of high quality applications outstripping the dollars that are available.

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In recent years, many individuals have approached us to discuss what is ostensibly a problem in peer review. The problem, however, turns out not to be a failing in the peer review process, but rather the fact that an individual with a 185 priority score didn't get funded because the Institute to which the application was assigned was funding at 175 that round. While this is not a failing in the peer review system, it may be a failing in the way we express the result of peer review, specifically an over-dependency on the third digit in the priority scores.

The sliding scale has been one of the proposals to get away from the all or nothing event right at the funding margin.

Comment: The sliding scale makes it possible for a broader range of deserving research projects to be funded. We are not only talking about people with a score of 180 being turned down, but about people with a score of 157 not being funded. Some of these people, whom I know, are established investigators. This has to be changed. We must become mentally ready to accept some modification in the all or nothing system.

NIH Response: One suggestion has been to make sure that half of the people approved get something.

Comment: That seems to be a reasonable goal.

NIH Response: Your commentary has been very helpful. Clearly the NIH can't ignore the kinds of changes that are going on and the new vulnerabilities to which all of our systems are exposed. What worked well when we were able to fund 50 percent or more of the approved applications is not necessarily the way to go about our business with the kind of competition we are now seeing.

5. Workload Responses

a. Not Rereviewing Unfunded Applications with Excellent Priority Scores

NIH Comment: We are concerned about rereviewing applications that originally had excellent priority scores, for example, between 100 and 200; and we are seeing increasing numbers of these applications. Is it really cost effective to rereview such applications when the problem is not scientific weaknesses in the applications but available funds? We are debating whether to have a cutoff score for revised applications.

Question: What happens to such applications?

NIH Response: They would remain for consideration for funding at the next council meeting, but would not be rereviewed by a scientific review group. This would alleviate some of the workload in the review groups.

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Comment: I take exception to that. Unless an application has a serious chance at funding, I think that is adding insult to injury. If you allow only applicants with applications higher than 200 to resubmit, but not those between 100 and 200, you are penalizing applicants who have good applications and who should have been funded in the first place had it not been for the budget.

NIH Response: But when an applicant with a 179 score tries to revise the application and reviews the summary statement, there is usually nothing to revise. They call us up and say, "What is wrong with my application? The critique says it is a good application."

Comment: That is clearly an excellent score, but I can't imagine that a score of 179 would not have associated with it certain comments suggesting how the application could be approved. If the application were perfect, it would have gotten 100. There must be some information that would help the applicant in revising the application.

NIH Response: That isn't always true. Often the priority falls because of a few negative comments during the discussion, which isn't reflected in the summary statement.

Comment: The problem is that you have 18 people sitting around the room giving a priority score. Some people are going to feel, without any identifiable, documentable reason, that one application is not as good as another and give it a 2.0 instead of a 1.0.

b. Institutes Retaining Unfunded Applications in Active Status Over More than One Funding Cycle

Comment: I am concerned about Institutes carrying over applications from one funding cycle to the next. Scientific review groups are not the same from one time to the next. I think it is a dangerous procedure, and I would like to hear what other people have to say about that.

NIH Response: You wouldn't want them all returned, would you? The intentions are good, that is to give the applicant a second or third shot.

Comment: But this has the disadvantage of preventing investigators from submitting competitive renewals. It also may be unfair to them by combining their scores with scores that were derived at a different meeting. Of course, this can be to their advantage as well as their disadvantage. But I think that a good clean cut is better than uncertainty.

NIH Response: Our general policy has been to encourage Institutes to carry over applications only if they are under active consideration for an award. While we have had some differences

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in interpretation as to the breadth of that zone, the Institutes, for the most part, are trying to be positive. If they can keep the application alive, give it another shot, and spare the principal investigator the time and effort of preparing another application, that is a track worth taking.

My best advice to an investigator is to discuss the situation with the Institute to which the application is assigned, and get the clearest possible reading about how close the application is to consideration for an award. Then the investigator can decide whether to withdraw or leave the application.

Question: Doesn't an investigator always have the alternative of having the application rereviewed and given a new priority score?

NIH Response: Yes, but technically you have to first withdraw the application. Unless there were some perceived flaw in the review process, we would have no particular inclination to rereview the application, particularly if you were not contesting what the peer reviewers said.

Comment: I understand your concern, but I don't think there is any reasonable way around the situation. The investigator always has the prerogative of withdrawing and resubmitting the application.

If the application is rereviewed, there may be new material that was not in the original application. Of course, this means more applications to review. One alternative might be the flexibility in awarding portions of applications; but barring that, this is a bad situation that we will have to live with.

c. Prescreening Applications

Question: Have you considered prescreening applications?

NIH Response: In the past, individuals have suggested a triage system where we would do prescreening. But to many of us here that is currently unacceptable, unless we could get the committee to develop a system for a quick type of review. The abbreviated review would replace lengthy discussions for those types of applications that have little chance of being recommended for approval or of receiving a good enough priority score to have a chance for funding. As of now, we don't feel that is an acceptable procedure in terms of peer review.

6. Revised PHS 398 Application Kit

NIH Comment: I would like to bring you up-to-date on the revision of the PHS 398 form, which is used to apply for most grant programs. As you know, about 2 years ago, after much input from the NIH and the scientific community, we revised

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that form and printed it in a different format. We have since then received a number of other suggestions from members of review groups, from the scientific community, and from NIH staff, and so we are currently revising it to clarify a number of points that were brought to our attention.

The revised form will reflect the new human subjects regulations, and there will also be increased emphasis on the information to be provided where animals are to be used in the research project.

Another area that we will emphasize is that applicants must clearly put any materials that are important to the review of their applications in the body of the application, and not hide them in appendices. We are currently having problems with applicants who complain that the study section didn't see the material that was in the appendix. But we do not duplicate appendices; we send them to primary and secondary reviewers and have them available to the review group at meetings.

We are also going to stress page limitations. We have published those page limitations for about 2 years now, and the scientific community has adapted to them. Sometime this sping, we will send out a notice in our Guide to Grants and Contracts that if an application does not meet those page limitations, it will be returned to the applicant. That means the application will be delayed a review cycle.

In terms of the preparation of the PHS 398, some of the applications that are submitted appear thrown together at the last minute. There often isn't any quality control at the institutions. We have been accepting most of these applications, leaving it to the Executive Secretaries to gather the additional information that is needed for review. In many cases, this basically comes down to rewriting the application for the applicant. We will now start returning those applications, because this is the applicant's responsibility, and we are faced with an increasing workload. Right now, we have in-house for the next round of scientific review group meetings our largest workload ever. We are going to have to do something to control that workload.

NIH Comment: Just to graphically illustrate what this workload means, during recent deadline periods, we have had in the Division of Research Grants 30 to 35 cubic meters of paper that applicants submitted. We are physically being inundated with paper, and we must do something.

Question: Do you anticipate any problems in reconciling, on the one hand, an emphasis in placing additional information in the text of applications with, on the other hand, a greater stress on page limitations?

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NIH Response: We do see some problems, but some investigators have been putting illustrations, charts of various types, graphs, and chemical sequences for synthesis of new chemicals in appendices where they have been overlooked. Therefore, charts, illustrations, or chemical syntheses that are part of the body of an application will not usually count against page limitations. We will do things like that to accommodate applicants.

NIH Response: Basically, we are trying to challenge people to write succinctly and yet completely.

Question: Have you considered asking the applicant to submit more copies of each appendix to make sure all of the review group members get copies?

NIH Response: Right now, they give us an original and six copies of the applications and the appendices. If we ask the institution or investigator to duplicate appendices, which often constitute a very large package, we will be pushing up the cost to the institution, which also pushes up our indirect cost rates. And we are trying to control indirect costs.

Question: When do you anticipate the revised form?

NIH Response: The revised form will probably come out towards the end of the year. But most of the material that I have mentioned, such as the page limitations, is already in the current instructions.

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Comment: I would like to place a strong plea in for strengthening the section that talks about justification of budget personnel and equipment. For at least half of the applications that I have been assigned, I have to ask the Executive Secretary to get additional information from the principal investigator.

Comment: Perhaps we should send applicants model applications. That would probably answer questions about the required budget details, about the specific aim of an experiment, or about the significance section. Instead of sending in statements about what should be done, how many pages and in what detail, we could provide a sample of what an application should be.

NIH Response: I think it is a good idea to have model applications, either in the kit or available to be widely disseminated. If we don't give applicants some kind of page limitations, I am confident calamity will result. The piles of paper are getting larger.

Comment: It is my impression that if we show applicants how it is done, they will do it.

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Question: Can you provide additional guidelines about how NIH will respond when investigators do not stick to the length constraints or submit incomplete applications? Also what sort of discipline can we exercise?

NIH Response: In the past we have gone out of our way to help investigators. We have duplicated applications when the original and six copies are missing, and have typed out three-part cards that have not come in.

But with the increasing workload, we no longer have the resources to provide these services. We have a form letter now alerting investigators, when they have not submitted the appropriate number of copies, that they have 10 working days to make up the deficiency. Otherwise, they run the risk of being deferred. Perhaps we ought to extend this to the three-part card.

On the other hand, we recognize what is going on out in the field. Occasionally, when we see applications that exceed the page limit in certain sections, we have been lenient, because we realize the unnecessary delays and extra postage in sending back applications. But the number of applications that exceed page limits significantly are very few; we have only had one case this last round. We are reluctant, quite frankly, to return an application that exceeds a page limitation by only half a page or three quarters of a page. Where an applicant exceeds the limitation by 10 pages, that is another ball game. But we are trying not to be bureaucratic, but to deal with cases in a reasonable fashion.

Comment: While I sympathize with those who go over the limit, I think we punish those who stick to the rules when you bend over backwards for those who don't. I feel that we should return applications from people who don't live up to your guidelines. Many other people are working hard to condense their proposals into the space allocation.

Comment: I feel that if we are going to insist on the page limitations, we should allow some investigators to write a very brief background. I do not mean the incredible literature reviews that we used to have, but there are a number of areas where investigators moving into new areas will penalize themselves if they cannot write two or three pages of background.

Comment: This is a minor suggestion. We are explicit about how the bibliography is to be listed, by number and in order of appearance. I don't like the abbreviated bibliography form in the text, with just the authors and the journal. If I am looking in the back of the descriptions to see if they have the right references, I must remember the title. While this is all right for a study in my area of expertise, in other areas this presents difficulties. I know this practice was designed to save space, but I think it is more useful and convenient to have complete references.

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NIH Response: A sentence in the newly revised instruction states that titles would be useful. In response to comments such as yours, we have encouraged, though not required, titles to be incorporated in the text.

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APPENDIX A

LIST OF PARTICIPANTS

AT THE MEETINGS

MEETING I
Monday, February 1, 1982
10:00 a.m. - 3:00 p.m.
Wilson Hall, Building 1
National Institutes of Health

STUDY SECTION	CHAIRPERSON	EXECUTIVE SECRETARY
Aging Review Committee (NIA)	Dr. Charles R. Ross	Dr. Walter Spieth
Allergy, Immunology & Transplantation Research Committee (NIAID)	Dr. Eng M. Tan	Dr. Nirmal K. Das
Behavioral & Neurosciences Study Section, DRG	Dr. Thomas E. Ogden	Dr. Bertie Woolf
Biomedical Sciences Study Section, DRG	Dr. Stanley Zimmering	Ms. Joan Fredericks
Biometry & Epidemiology Contract Review Committee (NCI)	Dr. C. Frank Starmer	Dr. Wilna A. Woods
Breast Cancer Task Force Committee (NCI)	Dr. Moyses Szklo	Dr. D. Jane Taylor
Cancer Clinical Investigation Review Committee (NCI)	Dr. Joseph V. Simone	Dr. Dorothy Macfarlane
Cardiovascular & Renal Study Section, DRG	Dr. James T. Willerson	Dr. Rosemary Morris
Clinical Cancer Education Committee (NCI)	Dr. Daisilee H. Berry	Dr. Margaret Edwards
Clinical Sciences Study Section, DRG	Dr. Fred Rapp Dr. John W. Kendall	Dr. Lynwood Jones
Communicative Disorders Review Committee (NINCDS)	Dr. Maxwell Abramson	Dr. Marilyn Semmes
General Clinical Research Centers Committee (DRR)	Dr. Charles Hollander	Dr. Ephraim Levin
General Research Support Review Committee (DRR)	Dr. Frances V. McCann Dr. William E. Moore	Dr. Sidney McNairy
Human Resources & Research Review Group A (NIADDK)	Dr. George F. Odland	Dr. Richard Pledger
Human Resources & Research Review Group B (NIADDK)	Dr. David Schachter	Dr. Rosemarie Petrucelli
Large Bowel & Pancreatic Cancer Review Committee (Large Bowel Subcommittee) (NCI)	Dr. Edward M. Copeland, III	Dr. Vincent Cairoli
Mammalian Genetics Study Section, DRG	Dr. Roy D. Schmickel	Dr. Jerry Roberts
Maternal & Child Health Research (NICHD)	Dr. T. Terry Hayashi	Dr. Jane Showacre
Mental Retardation Research Committee (NICHD)	Dr. Charles J. Epstein	Dr. Stanley Slater
Microbiology & Infectious Diseases Advisory Committee (NIAID)	Dr. R. Walter Schlesinger	Dr. Susan Spring
Minority Access to Research Careers Review Committee (NIGMS)	Dr. Curtis L. Patton	Dr. Harriet Gordon
Population Research Committee (NICHD)	Dr. Georgiana Jagiello	Dr. Dinesh Sharma
Research Manpower Review Committee (NHLBI)	Dr. Karen Hitchcock	Dr. Charles Turbyfill

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MEETING II
Monday, February 8, 1982
10:00 a.m. - 3:00 p.m.
Wilson Hall, Building 1
National Institutes of Health

STUDY SECTION	CHAIRPERSON	EXECUTIVE SECRETARY
Animal Resources Review Committee (DRR)	Dr. Dale D. Boyd Dr. Hyram Kitchen	Dr. Carl E. Miller
Bacteriology & Mycology I Study Section, DRG	Dr. Zell A. McGee	Dr. Milton Gordon
Behavioral & Neurosciences Study Section, DRG	Dr. William Norton	Dr. Laura Weinstein
Biomedical Sciences Study Section, DRG	Dr. Keith Moffat	Dr. Charles Baker
Biopsychology Study Section, DRG	Dr. Stephen Glickman	Dr. A. Keith Murray
Blood Research Review Group, DRG	Dr. John F. Bertles	Dr. M. Wayne Hurst
Cancer Control Intervention Programs Review Committee (NCI)	Ms. Mary C. MacVicar	Dr. Eugene Zimmerman
Chemical Pathology Study Section, DRG	Dr. Thomas J. Slaga	Dr. Edmund Copeland
Communicative Sciences Study Section, DRG	Dr. Barbara Bohne	Dr. Michael Halasz
Gastroenterology & Clinical Nutrition Study Section, DRG	Dr. Gabriel Makhlouf	Dr. Samuel Abramson
Human Embryology & Development Study Section, DRG	Dr. Douglas Kelly	Dr. Arthur Hoversland
Microbial Genetics Review Group, DRG	Dr. Frank Young	Dr. Gerald Liddel
Molecular Biology Study Section, DRG	Dr. William E. Hahn	Dr. Donald Disque
Molecular Cytology Study Section, DRG	Dr. Donald A. Fischman	Dr. Ramesh Nayak
Neurology A Study Section, DRG	Dr. Robert S. Bourke	Dr. Catherine Woodbury
Nutrition Study Section, DRG	Dr. Dennis M. Bier	Dr. John Schubert
Pathobiological Chemistry Study Section, DRG	Dr. Paul Bornstein	Dr. Clarice Gaylord
Pathology B Study Section, DRG	Dr. Joe W. Grisham	Dr. M. Padarathsingh
Physiology Study Section, DRG	Dr. Robert S. Eisenberg	Dr. Martin Frank
Respiratory & Applied Physiology Review Group, DRG	Dr. Lowell Stone	Dr. Nathan Watzman

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Proceedings of the 1981 Meetings of the Chairpersons of NIH Scientific Review Groups

Prepared by:
Division of Research Grants

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service National Institutes of Health

7. Review of Applications from Members of Scientific Review Groups

Comment: I'm seeing a reluctance of people to serve on a study section because they assume that for the next 4 years they will not be able to obtain funding for their own work, no matter how good their proposal is. And with the increasing problem of high-priority scores not being funded, I think we're facing real problems in how the peer review system is going to work.

Dr. Douglass: When you say that they believe their applications will not be funded, is that because of a general concern about the amount of resources which will be available or because of a feeling that they're at some kind of a disadvantage?

Comment: A disadvantage, because their applications will not go to the regular study sections.

Dr. Douglass: In response to your concern and a similar question raised during the last series of Chairpersons Meetings, we have done a small study of our experience with the review of study section members' applications over the five-year period, 1974 through 1979. This is only one approach to this issue, and we may be doing another study next year. Let's look at the first slide (Figure 2).

Figure 2

COHORTS OF DRG STUDY SECTION MEMBERS STUDIED
STATUS OF APPLICATIONS REVIEWED, RELATED TO TERMS OF SERVICE

	COHORT A	COHORT B	COHORT C	COHORT D
YEAR OF SERVICE ON STUDY SECTION IN CY 1977 IS THE	1ST	2ND	3RD	4TH
YEAR APPLICATIONS REVIEWED	1977	1977	1977	1977
CY 1975	■	■	●	●
CY 1976	■	●	●	●
CY 1977	●	●	●	●
CY 1978	●	●	●	▲
CY 1979	●	●	▲	▲

■ BEFORE SERVICE ● DURING SERVICE ▲ AFTER SERVICE

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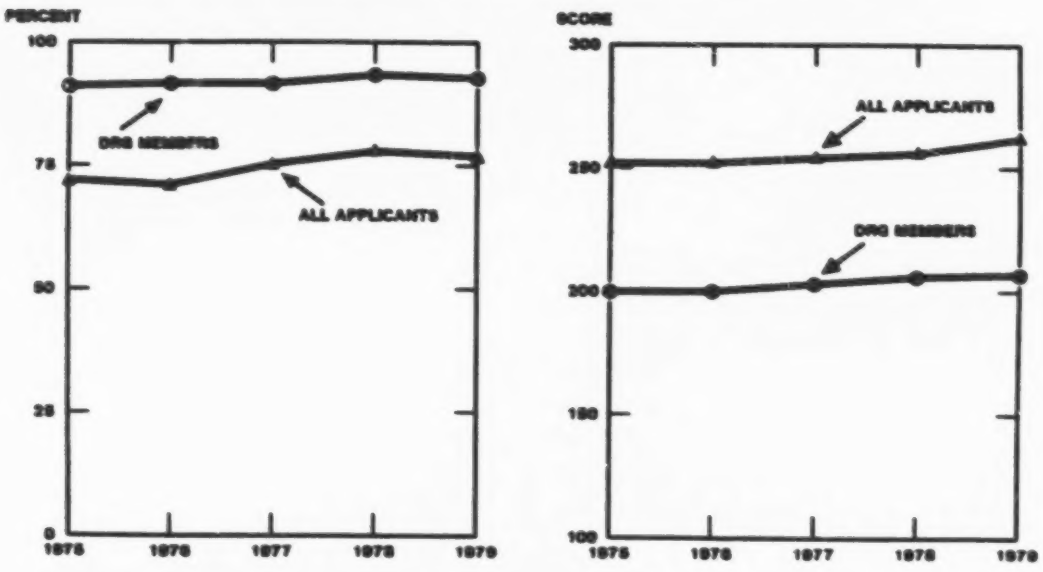
We examined all applications that were reviewed in the Division of Research Grants, from calendar years 1975 through 1979. Then we took all applications from principal investigators who were study section members in 1977, and divided this population of study section members into four cohorts. Those who were serving in Cohort A were serving their first year in 1977, and continued serving during 1978 and 1979. Cohort B began service in 1976, and their last year of service would have been 1979. Cohort C's last year of service would have been 1978, while that of Cohort D would be in 1977. Therefore, we looked at applications from study section members who submitted applications and had them reviewed during their period of service (dots), before their period of service (squares), and after their period of service (triangles).

In this preliminary study, if you look at DRG study section members' approval rates over this five-year period, you will see that they were between 90 and 100 percent, whereas the approval rate for the whole population, all applicants, was down around 75 percent (Figure 3). If you look at the priority scores over this period, you will see that all applicants had average priority scores beginning about 250 and climbing up to about 262, whereas those who were members of study sections had average priority scores of around 200. Let me emphasize that this was not unexpected. You were chosen because you had, were expected to continue to have, and in fact, continued to have good records. Therefore, there is nothing unusual about this distribution.

Figure 3

APPROVAL RATES AND AVERAGE PRIORITY SCORES OF APPLICATIONS OF DIVISION OF RESEARCH GRANTS (DRG) STUDY SECTION MEMBERS AND ALL APPLICANTS REVIEWED IN DRG CY 1975 - 1979



CHARTERED STUDY SECTIONS; REGULAR MEMBERS, SERVING IN CY 1977

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As you can see in these next two slides (Figures 4 and 5), the approval rates are high, if they went to the same study section in which the member served or was to serve. If they went to a different study section, the rates are slightly less; but if you look at the period when they are actually serving on study sections, you see an improvement in that approval rate. If the applications went to an ad hoc study section, again there is a pretty good approval rate, and the same is true with special study sections.

This pattern follows all the way through, and I won't belabor you with details beyond saying that we were unable to see any disadvantage that anyone incurred, when compared to the general population of applications, by coming on a study section either by priority score or by approval rate. Except for a few anomalies because cell sizes are small, study section members' priority scores are running right at 200 while there is a 250 average priority score across all applications. The approval rates are about 75 percent across all applications, but usually better than 90 percent for study section members. There is generally no change before or after service.

Looking over the distribution of priority scores in a a particular year, in calendar year 1975, DRG study section members were between 150 and 199, whereas the others are scattered with a long tail to the right (Figure 6). Generally this same pattern holds true for the other years. We can't find that you are in any disadvantage for serving on the study sections in relation to review of your own applications. Are there any comments or questions?

Question: What is current DRG policy?

Dr. Douglass: Current DRG policy is that your applications cannot go to your study section while you are a member. We will find another group to review them, either another study section with equal expertise or a special study section.

Comment: I have served on several of these ad hoc committees to review applications for members of study sections, and I think that because it is a one-time affair, the review is subject to more chance of error than with the individual's own study section. Consequently, I suggest that if there is a related study section with relevant expertise, the application go to that study section. That would be my first choice.

Now, if that cannot be implemented and it is necessary to set up a special study section, then the key point is the character of that study section. The executive secretary of the study section where the applicant serves should be consulted, because the executive secretary is fully aware of that person's work and also knows the other people with expertise in the area. Obviously, that executive secretary cannot be

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Figure 4

MEMBERS OF DRG STUDY SECTIONS (REGULARLY CHARTERED) WHOSE APPLICATIONS WERE ACTIVE CY '77 AND WHO HAD NIH APPLICATIONS REVIEWED CY 75-79

	CY	AVERAGE PRIORITY SCORE: SAME* IRG		DIFF IRG		AD HOC		SSS		IRG APPROVAL RATE: SAME* IRG	DIFF IRG	AD HOC REV	SSS
COHORT A	75	177	(43)	197	(33)	197	(3)	168	(2)	97.7	97.1	100.0	100.0
	76	178	(28)	226	(19)	321	(1)	258	(1)	96.6	78.2	100.0	100.0
	77	182	(37)	218	(44)	190	(3)	231	(7)	100.0	96.3	100.0	100.0
	78	263	(3)	192	(58)	190	(14)	221	(22)	100.0	96.7	100.0	86.0
	79	173	(1)	201	(51)	206	(15)	178	(15)	100.0	96.1	86.2	86.2
		181	(112)	203	(205)	201	(36)	207	(47)	96.2	92.8	94.7	90.4
COHORT B	75	199	(37)	211	(29)	379	(1)	-	(-)	97.4	96.7	100.0	-
	76	168	(19)	222	(16)	203	(1)	223	(5)	100.0	76.2	100.0	83.3
	77	-	(-)	224	(55)	325	(1)	186	(12)	-	94.8	50.0	92.3
	78	126	(1)	222	(56)	229	(8)	211	(18)	100.0	86.9	86.9	100.0
	79	145	(2)	225	(46)	221	(9)	211	(19)	100.0	92.0	90.0	95.0
		166	(59)	222	(202)	236	(20)	209	(54)	96.3	91.0	87.0	94.7

Figure 5

MEMBERS OF DRG STUDY SECTIONS (REGULARLY CHARTERED) WHOSE APPLICATIONS WERE ACTIVE CY '77 AND WHO HAD NIH APPLICATIONS REVIEWED CY 75-79

	CY	AVERAGE PRIORITY SCORE: SAME* IRG		DIFF IRG		AD HOC		SSS		IRG APPROVAL RATE: SAME* IRG	DIFF IRG	AD HOC REV	SSS
COHORT C	75	198	(25)	203	(36)	226	(5)	168	(2)	96.2	73.5	100.0	50.0
	76	136	(2)	209	(54)	-	(-)	233	(8)	100.0	96.4	-	88.9
	77	-	(-)	214	(61)	188	(5)	229	(16)	-	92.4	100.0	88.9
	78	-	(-)	215	(53)	263	(6)	199	(17)	-	89.8	88.9	89.5
	79	211	(3)	203	(59)	267	(18)	198	(13)	100.0	96.2	100.0	96.7
		196	(30)	209	(263)	246	(36)	211	(56)	93.8	90.1	97.3	88.2
COHORT D	75	-	(-)	205	(26)	173	(4)	169	(7)	-	92.9	100.0	87.5
	76	342	(2)	184	(27)	147	(1)	203	(15)	100.0	90.0	100.0	93.3
	77	-	(-)	209	(44)	138	(2)	224	(20)	-	88.8	100.0	90.9
	78	185	(4)	209	(35)	242	(5)	215	(19)	100.0	97.2	100.0	95.0
	79	151	(29)	193	(18)	218	(10)	157	(2)	96.7	88.7	100.0	100.0
		166	(35)	202	(150)	205	(22)	208	(63)	97.2	91.8	100.0	90.0

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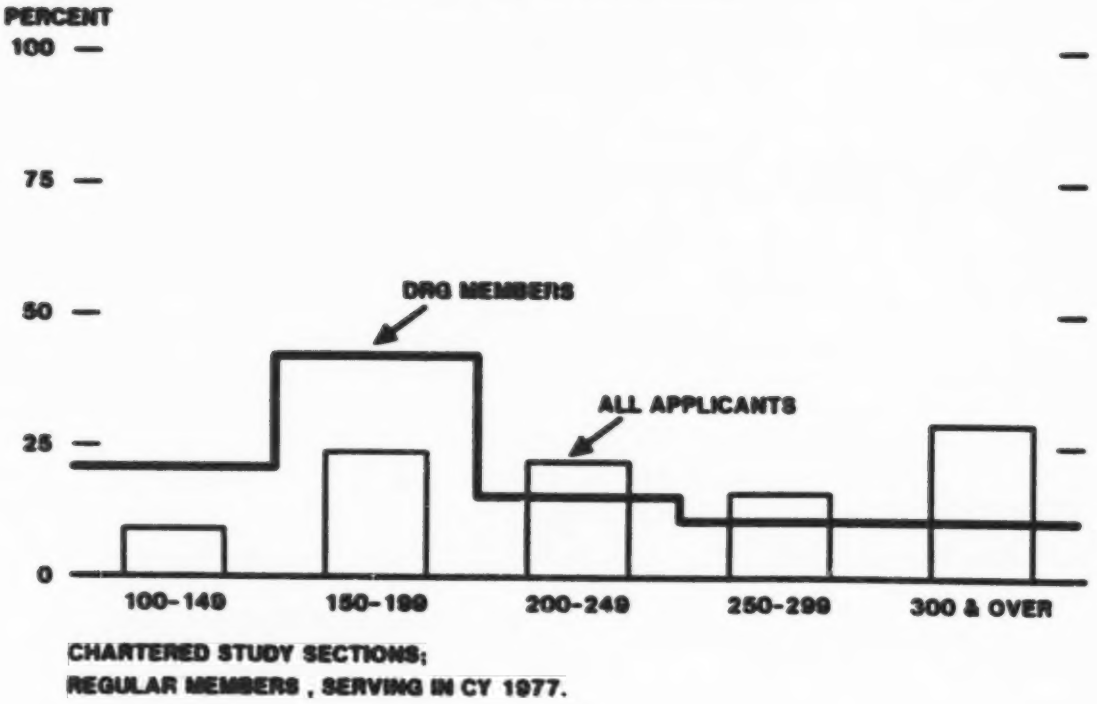
Figure 6



the executive secretary of the ad hoc group, but that individual should consult with the executive secretary for input as to the composition of the committee. I have seen cases in which people with a lack of expertise reviewed an application; I don't know if it did any harm, but in my book it is not good for people who have no expertise in the matter to review a grant application.

Dr. Douglass: If any of you find yourselves in such a situation, I hope you will call it to my attention and we'll straighten it out.

The problem in a special study section is a lack of continuity. If we put together a special study section to review an application from someone, we are allowed to have on that study section no more than 50 percent of currently serving members on the applicant's study section. Also, the NIH is perfectly willing to let the investigator know the names of the people serving on a review group prior to the review. And I would encourage, especially if the application goes to a special study section, that you find out who the members of the review group are; and if you feel that review group is inappropriate, then let us know. One of the things that gives us a great deal of trouble is when we don't hear from the investigator until after the review.

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